

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

**PAR PHARMACEUTICAL, INC.,
 PAR STERILE PRODUCTS, LLC,
 and ENDO PAR INNOVATION
 COMPANY, LLC,**

**CIVIL ACTION NUMBER:
 3:18-cv-14895-BRM-DEA
 MARKMAN HEARING**

Plaintiffs,

v.

SANDOZ, INC.,

Defendants.

Clarkson S. Fisher Building & U.S. Courthouse
 402 East State Street
 Trenton, New Jersey 08608
 January 21, 2020
 Commencing at 9:32 a.m.

B E F O R E:

**THE HONORABLE BRIAN R. MARTINOTTI,
 UNITED STATES DISTRICT JUDGE**

A P P E A R A N C E S:

DECHERT, LLP
 BY: ROBERT D. RHOAD, ESQUIRE
 502 Carnegie Center, Suite 104
 Princeton, NJ 08540
 For the Plaintiff

DECHERT, LLP
 BY: MARTIN J. BLACK, ESQUIRE
 BRIAN M. GOLDBERG, ESQUIRE
 SHARON K. GAGLIARDI, ESQUIRE
 Cira Centre, 2929 Arch Street
 Philadelphia, PA 19104
 For the Plaintiff

Megan McKay-Soule, Official Court Reporter
 megansoule430@gmail.com
 (215) 779-6437

Proceedings recorded by mechanical stenography; transcript
 produced by computer-aided transcription.

A P P E A R A N C E S:

HILL WALLACK, LLP
BY: ERIC ABRAHAM, ESQUIRE
NAKUL SHAH, ESQUIRE
21 Roszel Road
Princeton, NJ 08540
For the Defendant

BRINKS, GILSON & LIONE
BY: LAURA LYDIGSEN, ESQUIRE
MARK REMUS, ESQUIRE
455 North Cityfront Plaza Drive
Suite 3600
Chicago, IL 60611
For the Defendant

1 (PROCEEDINGS held in open court before The Honorable
2 BRIAN R. MARTINOTTI, United States District Judge, on January,
3 21, 2020, at 9:32 a.m.)

4 THE COURT: Okay. Good morning, everyone. You may
5 be seated.

6 MR. BLACK: Good morning, Your Honor.

7 THE COURT: Counsel, your appearances for the record.

8 MR. RHOAD: Good morning, Your Honor. Robert Rhoad
9 from Dechert, LLP here on behalf of the plaintiffs. With me
10 here this morning is Martin Black, a colleague of mine, as
11 well as Sharon Gagliardi.

12 MR. ABRAHAM: Good morning, Your Honor. My name is
13 Eric Abraham from Hill Wallack in Princeton, New Jersey. I'd
14 like to introduce the Court to my co-counsel, Mark Remus.

15 MR. REMUS: Good morning, Judge.

16 MR. ABRAHAM: Laura Lydigsen. I'd also like to
17 introduce the Court to my client, Paki Banky, from Sandoz and
18 also Nakul Shah, a young associate at my firm Hill Wallack.

19 THE COURT: Welcome.

20 MR. RHOAD: So Your Honor is aware, our client, Guy
21 Donatiello, is here as well this morning.

22 THE COURT: Welcome. You're going to go visit Judge
23 Arpert after this, I believe.

24 MR. BLACK: Yes, sir.

25 THE COURT: What did we block out? Two hours?

1 THE DEPUTY COURT CLERK: Yes, sir.

2 THE COURT: So I have read everything over the
3 weekend, twice. This is your hearing. I'll let you proceed
4 as you see fit.

5 MR. BLACK: Thank you, Your Honor.

6 Martin Black. I think what we'd like to do is we have
7 four terms, and we've agreed to argue term by term. So I will
8 start by addressing just to give you a little brief background
9 information and then jump into the first term, administering,
10 and then they'll respond to that and then we'll ping-pong back
11 and forth.

12 THE COURT: Why shouldn't I follow in Judge
13 Connolly's well-reasoned decision?

14 MR. BLACK: Well, Your Honor, since he ruled in our
15 favor I believe that you should. I believe that you should.

16 THE COURT: Okay.

17 MR. BLACK: So I also think it's an easy one in the
18 sense that if you just look at claim 16 of the -- I'll jump
19 right to it. Hold on a second.

20 So the core of Sandoz's argument is really on this
21 slide here, which is -- which shows their -- they have a
22 number of statements in their brief where they say that
23 there's no reference to dilution anywhere in the claim. These
24 claims say nothing about dilution. There is not mention of
25 dilution or IV drip while the patents are silent on dilution.

1 But I guess claim 16 says the pharmaceutical composition is
2 diluted in a diluent. And what they've really done is try to
3 raise the same argument in Delaware just without using the
4 word "dilution," and we think on its face, the claims show
5 that that is not correct.

6 If we go back and look generally just at how this
7 product is administered, vasopressin comes in a vial. It is
8 stored -- the claims require storage for four weeks,
9 refrigerated conditions when it's needed, typically in an
10 emergent situation where a doctor needs to raise the blood
11 pressure quickly, it's injected into an IV bag and then
12 administered to a patient at a particular rate.

13 THE COURT: Talk to me about why it was only
14 mentioned in the '239 and nowhere else.

15 MR. BLACK: Sure, Your Honor. The '239 is limited to
16 dilution. The other patents are not limited. So there is a
17 -- I'll call it a core case, a rare situation where the drug
18 can be administered right out of the bottle with a syringe.
19 It doesn't make any sense in the context of these claims which
20 require administration at a very particular rate of .1 to 1
21 unit per minute. You can't sit there with a syringe and
22 administer something at a rate. A human being doesn't do
23 that. And the evidence is that this particular drug is almost
24 always administered in diluted form.

25 So what the claim says is it has a -- the first part of

1 the claim -- the first part of the claim discusses the
2 characteristics of the product. Let me just give you the
3 right number slide. We are on slide 12.

4 So this is the structure of the claim. It's '526,
5 claims 1, dependent claim 16 to 19.

6 It's a method for increasing blood pressure, and it has
7 several steps. The first step is providing a pharmaceutical
8 composition for intravenous administration, and then it has a
9 number of parameters. The concentration. It has acetic acid.
10 It has water. It has a pH of 3.8, and that's what you get in
11 the vial. Then the second step is storing the composition at
12 2 to 8 degrees celsius for four weeks in the refrigerator.
13 And then the third step is actually in claim 16 which says
14 diluted in a diluent prior to administration. And then the
15 fourth step is intravenously administering where the
16 administration is at a particular rate, not a particular
17 concentration.

18 So the whole claim fits together and the patent
19 specification discusses exactly this. It talks about the
20 method and how you perform the method. It's a method of
21 administration. There's nothing in the patent that explicitly
22 discusses this unusual case where you inject it directly.
23 It's just -- it's known in the specification. It's discussed.
24 And the one example given of how to administer it is dilution
25 in an IV bag. And we also submitted evidence indicating that

1 that's the way it's done in the real world. So people reading
2 the specification would understand that you can either dilute
3 or not dilute. The important thing is that the medicine gets
4 into the patient. It's a little like somebody said take an
5 Alka-Seltzer. You don't just swallow one. You put it in the
6 water, let it dissolve, and then drink the solution. That's
7 what doctors know. That's what their specification describes.

8 THE COURT: I understand your argument on this point.

9 MR. BLACK: Thank you.

10 THE COURT: Counsel, why shouldn't I follow Delaware?

11 MR. REMUS: The reason you should not follow Delaware
12 is that the claim construction that Sandoz is advancing is
13 materially different from the claim construction that Eagle
14 advanced and that Judge Connolly ruled on. On this slide,
15 this is slide 8, Your Honor. This is Eagle's construction
16 that they proposed. It is identical to Sandoz's construction
17 except in one very important way, and that's the red
18 parenthetical. Eagle asked Judge Connolly to expressly hold
19 that the claim does not cover dilution before administration.
20 Sandoz's construction is completely silent regarding dilution.
21 Importantly, it does not exclude dilution. I want to explain
22 this because I think it's a very important point for framing
23 this dispute.

24 So if we go to slide 6, you've seen our construction
25 words. I think sometimes it helps to see it in images and how

1 this is administered in the real world.

2 Sandoz's construction is very straightforward, and that
3 is for all of these claims that require administering, you
4 have to administer the formulation having the properties that
5 are required in the claim.

6 And so if we go to -- for example, this is claim 1 of
7 the '209 on slide 5, you'll see the green highlighted subject
8 matter are the three specific properties that are required for
9 the formulation. One of those properties -- we see this come
10 up frequently -- is a specific concentration of vasopressin.
11 Here, it's .01 to .07 milligrams per milliliter. So if we
12 take that and go to the real world application, what Sandoz's
13 saying is when that formulation is administered to the
14 patient, when it's put into that patient's vein, it has to
15 have that concentration that's expressly stated in the claims.

16 Now, what about dilution? We'll go to slide 7. This
17 is how Sandoz's construction applies to dilution. If you take
18 a bottle of vasopressin, for example, which is showing that
19 bottle on the left, dilute it with dextrose or saline,
20 whatever you want, and then administer it to a patient, that's
21 fine. Sandoz's construction does not exclude that. But if
22 you do that, you still need to have the concentration of
23 vasopressin that's required in the claims.

24 So you can dilute all you want, but you still have to
25 meet the elements in the claims.

1 That is something that Judge Connolly never ruled on.
2 He focused his attention on whether you should exclude or
3 include dilution. He did not rule on this issue of requiring
4 the formulation to have the properties required in the claim.
5 So in that regard, this Court is writing on a blank slate.

6 Now, I want to contrast Sandoz's construction with
7 Par's construction. And this is on slide 9 and just a graphic
8 representation of how their construction applies in the real
9 world. Par says, starting on the left, you can start with a
10 bottle of vasopressin that has that claimed concentration of
11 .01 to .07 milligrams per milliliter. You dilute it and then
12 you get a completely different concentration that you
13 administer to the patient. In that regard, they're completely
14 ignoring the concentration that's required in the claims
15 because the concentration that's actually administered to the
16 patient is different than what's in the claim. Sandoz submits
17 that's wrong. It's ignoring the plain meaning of the words.

18 One thing that Mr. Black just mentioned that I want to
19 make clear is -- let me go to the next slide -- the
20 specification. I believe Mr. Black said -- so we're on slide
21 18 now -- what slide 18 shows is exemplary embodiments from
22 the '223 patent. One embodiment is an embodiment that does
23 not mention dilution. The other embodiment is one that
24 expressly mentions dilution. And we compare and contrast
25 these two on the screen where in green we've highlighted the

1 properties of the formulation. In yellow it's the
2 administering step.

3 The same holds true for the dilution embodiment where
4 green is the unit dosage form properties, light green are the
5 diluted unit dosage form properties. And if you look at that
6 light green highlighting, you'll see that the step is diluting
7 the unit dosage form in a diluent to provide a concentration
8 from about .1 to about 1 unit per milliliter. Then it
9 specifically says by way of milligrams, .21 micrograms to
10 about 2.1 micrograms. So a much different concentration than
11 what is present in the unit dosage form.

12 Here they're specifying these are two completely
13 different families of embodiments. And if we look at the
14 *Haemonetics* case as an example, the federal circuit explained
15 when you have one set of embodiments that tracks one set of
16 claims, and another set of embodiments that tracks another set
17 of claims, such as the '239 patent, you should not conflate
18 the two. Unit dosage form means something different from
19 diluted unit dosage form.

20 Mr. Black's comments about the specification describing
21 -- I believe he said referred to an IV bag -- not true. You
22 are not going to find any description of an IV bag, an IV
23 push, a syringe pump anywhere in the specification. Instead,
24 the description of the embodiment is identical between the
25 embodiments with no dilution and the embodiments with

1 dilution. And we've heard example to -- slide 18 again -- the
2 highlighted and yellow orange color, it's the exact same level
3 of detail for each embodiment. It simply says either
4 administering the pharmaceutical composition to the human or
5 administering the diluted unit dosage form to the human.

6 So that dilution embodiment is not providing any
7 additional detail. It's the exact same level of detail. The
8 only difference is what's the concentration of vasopressin in
9 that formulation? The dilution embodiment is not just a more
10 specific example of a general embodiment. It's a completely
11 different embodiment. The reason why that is, there are
12 different concentration ranges.

13 And I think that comes into play also when we look at
14 -- I'm at slide 16 now. Slide 16 is a comparison of claim 1
15 of the '526 patent to claim 1 of the '239 patent. Again, same
16 highlighting structure where the properties are highlighted in
17 green, the diluted properties are highlighted in light green.
18 And the point I want to make here is that claim 1 of the '239
19 is not just a more specific example or a narrower version of
20 claim 1 of the '526 patent. It's a completely different
21 embodiment because it has different concentrations. If claim
22 1 of the '239 was simply a more narrow version, you could not
23 infringe the '239 patent without also infringing the '526, but
24 that's not the case. Because it has a different concentration
25 range, one can infringe the '239 but not infringe the '526.

1 So they don't have this relationship where it's just more
2 specificity. Completely different embodiments, Your Honor.

3 One thing that Par really relies heavily on in its
4 briefs that I strongly disagree with is this notion of a
5 preferred embodiment. There's nothing in the specification
6 that describes any of these embodiments as more preferred than
7 another. The word "preferred" literally doesn't appear
8 anywhere in the hundreds of pages of these patents. They're
9 all treated equally, and the specification makes clear some
10 embodiments are protected by some claims, other embodiments
11 are protected by yet other claims.

12 Par relies a great deal, almost exclusively, on claim
13 differentiation as one of its strongest arguments. We cited
14 the case law in our briefs. Your Honor has read them. But
15 the federal circuit has made clear when you look at claim
16 differentiation, you can't let the dependent claim tail wag
17 independent claim dog. And that's exactly what Par is doing
18 in this instance.

19 THE COURT: How? How does the '239 wag the dog?

20 MR. BLACK: Because each claim, on its face, has its
21 plain ordinary meaning. Claim 1 of the '239, Your Honor,
22 slide 16, specifically defines the properties of the
23 formulation that is administered to the patient.

24 '526 again specifically defines the properties of the
25 formulation that's administered to the patient.

1 So if you're going to somehow read the '526 patent
2 claim 1 as covering administration of a diluted product,
3 you're changing the plain meaning because you're no longer
4 administering the concentration required in claim 1 of the
5 '526. You're now administering a completely different
6 concentration, and that's rewriting the claims. And that's
7 what Judge Dyk, in the *Baxalta* case specifically said you
8 can't do. He said, the court, the federal circuit has also
9 made clear that this rule of construction does not govern
10 where the independent claims on their face are of a more
11 limited scope. And that's what we have in all of these
12 patents. The claims are very clear on their face what the
13 concentration is that must be administered to the patient.

14 Last thing I want to touch on, Your Honor, is the role
15 of expert testimony here. Expert testimony cannot be used to
16 vary the plain meaning of the terms. Expert testimony can aid
17 construction but it cannot rewrite the claims. The situation
18 we have here is very similar to the situation that was present
19 in the *Chef America v. Lamb-Weston* case. This is summarized
20 on our slide 20.

21 The Chef America case concerned a claim directed to a
22 method of baking bread where you bake the dough to a
23 temperature of 400 degrees or more. The problem there is if
24 you bake bread to a temperature over 400 degrees it's burnt to
25 a crisp. It's a lump of charcoal. So in that case they

1 brought an expert in that says, well, we know that's what the
2 claims say, but we have an expert that says everyone knows
3 you're baking it at that temperature, not to that temperature.

4 And that's exactly what Par's doing in this case.
5 Notwithstanding the plain meaning of the claims, they say,
6 well, we have this expert and he says, well, everybody knows
7 that this is what you actually do in clinical practice, but
8 that's not what the claims said. You can't rely on expert
9 testimony to rewrite the plain meaning of the claims.

10 We think the claims are plain on their face, and we ask
11 the Court to adopt the construction where the properties
12 required in the claim are part of this claim construction.

13 THE COURT: Thank you.

14 MR. BLACK: Thank you, Judge.

15 THE COURT: Talk to me about concentration and
16 embodiments.

17 MR. REMUS: Yes, Your Honor.

18 If you look at their slide 18, you have that up there,
19 what he said was that the embodiment on the right reflects the
20 diluted form. And element C is diluting the unit dosage form
21 to a certain number of units, which is .21 micrograms per
22 milliliter to about 2.1 micrograms per milliliter. That's
23 what he says is the embodiment including dilution. And you'll
24 note that the dosage form begins at a concentration of .01
25 milligrams per milliliter to about .07. It's then diluted

1 down to .21 -- the little "u" is microgram -- to about 2.1
2 microgram. He says that's an example of dilution, which is
3 consistent with our theory.

4 Now, they filed their brief. We didn't get a chance to
5 file a reply. But if you'd like to take a look at slide 20,
6 Your Honor, of our presentation, you'll see in the claim set,
7 which is attached to the '526 claim 1, the dependent claims.
8 And claim 16 says the composition is diluted in the diluent.
9 That's the original composition at .01 to .07. Then claim 17,
10 which we didn't get to address because of the way the briefing
11 went, says, wherein the composition is diluted to another
12 concentration, .21 micrograms to 2.1 micrograms, which is the
13 example he gave in his presentation as something which is
14 diluted.

15 So you start in the vial with something at a particular
16 concentration in claim 1. It sits in a refrigerator for four
17 weeks. You take it out. You dilute it in claim 16. And you
18 dilute it to a specific concentration stated here. And we can
19 prove that's what happens.

20 Their theory is that, no, this claim set can only be
21 met if you keep the concentration at the original .01 to .07
22 and you have to measure it at the time that you are actually
23 -- lead the IV bag in the patient. That's not what this claim
24 set reflects. By his own admission, the specification, the
25 embodiment here that was intended by the patentee, was the one

1 with full dilution.

2 Now, these claims -- some of the claims can be read on
3 both. The point is you have to get what's in the vial, you
4 have to administer it and get it into the patient. The vast
5 majority of the time you're going to be diluted. Sometimes
6 you don't. That's very rare. And the claims that talk about
7 -- and almost all of them do -- about administering it to the
8 patient at a particular rate per minute really do reflect the
9 fact that this is something which is being administered
10 through an IV bag because people cannot sit there with a
11 syringe and administer something that deals with blood
12 pressure at a rate that -- human beings just don't do that.
13 So those of skill in the art understand that.

14 But the most important thing is, from a textual
15 perspective, we've got claims right here that involve
16 dilution. They cover the embodiment. There's no difference
17 between their construction here and the one in Delaware. All
18 they did was remove the parenthetical, which at least the
19 Eagle folks were honest enough to put into the -- to the
20 construction so that the Court would understand what everybody
21 was talking about. They've taken that out and it just has
22 kind of a tautology now. It just says it's administered
23 according to the concentrations in the claim. It's not
24 helpful. It's the same argument. Thank you.

25 THE COURT: Last word.

1 MR. RHOAD: I'll be brief, Judge.

2 First of all, his comments about administering a higher
3 concentration of vasopressin, it's possible. We submitted the
4 declaration from Dr. Coralic that discloses exactly how one
5 would go about doing it. So it is possible to practice the
6 claimed invention. Where I think Your Honor ultimately needs
7 to come out in considering all this evidence is Your Honor has
8 to weigh the various evidence. No one piece is dispositive.
9 We certainly think the plain meaning of the claims is most
10 important.

11 Mr. Black and Par keep beating the claim
12 differentiation drum. They have their cases where they say
13 claim differentiation controls. We have our cases that say it
14 doesn't control. At the end of the day, claim differentiation
15 is just an aid. It's not conclusive. It's one thing to
16 consider in the context of all the evidence. Sandoz submits
17 when Your Honor considers the plain meaning of the claims, the
18 specification and the prosecution history, that evidence shows
19 that Sandoz's construction is the correct one, rather than
20 Par's construction, which relies simply on the claim
21 differentiation. Thank you.

22 THE COURT: Thank you.

23 Next term.

24 MR. RHOAD: Good morning, Your Honor. Bob Rhoad for
25 the plaintiffs.

1 The next term we had lined up here is the term
2 vasopressin.

3 THE COURT: Okay.

4 MR. RHOAD: And so if we look at the parties'
5 proposed constructions, Par's proposed construction is
6 arginine vasopressin as described as a particular sequence ID
7 number, and Sandoz's is ordinary construction. That's the --
8 our proposed construction is the one that the parties
9 stipulated to in Delaware. So it's the one that governs in
10 Delaware and was not disputed in that case. So Judge Connolly
11 didn't make an affirmative ruling on the merits. It was just
12 accepted that that's the concentration.

13 So what's really the difference between the two? As
14 far as we can tell, the difference is, first of all, whether
15 or not it is arginine vasopressin, which is vasopressin that
16 is found in humans, or lysine, or does it also include things
17 like lysine vasopressin, which is a type of vasopressin found
18 in pigs.

19 The second part is whether or not what's required is
20 that it be synthetically prepared as opposed to naturally
21 derived. So those are really the two areas as a practical
22 matter where our --

23 THE COURT: What is defined in the ID?

24 MR. RHOAD: Arginine. Synthetic arginine
25 vasopressin. So --

1 THE COURT: And it's referenced.

2 MR. RHOAD: Yes. Yes.

3 So at the end of the patents there's roughly four pages
4 or so of these sequence listings, and that's a way for them to
5 specifically define, when they're referring to various
6 compounds, what exactly those substances are. And the very
7 first one is vasopressin which is sequence ID number 1.

8 And throughout the specification, they specifically
9 refer to vasopressin by way of its sequence ID number. So on
10 our slides we have a number of references. It says
11 vasopressin is a known peptide illustrated below sequence ID
12 number one.

13 Again, later on in the specification it says,
14 vasopressin and degradation are listed in table one below.
15 Table 1 below shows vasopressin sequence ID number 1.

16 Again, in table 3, it says it details the chemical
17 formula and structure of vasopressin and the tested
18 impurities. Again, it's by way of reference to sequence ID
19 number one.

20 And, again, later on, vasopressin is a white amorphous
21 powder. The structural form of vasopressin is sequence ID
22 number 1. So throughout the specification, they're referring
23 to vasopressin by way of a sequence listing, and that's the
24 whole reason why they put it in there, was to make clear when
25 they're talking about vasopressin for purposes of the claimed

1 invention, they're talking about what's listed in the
2 sequence.

3 So you go from there to do they identify it
4 specifically as arginine vasopressin? And in the sequence
5 listing, you see there on slide 38, it gives a sequence
6 listing and I put a box around Arg. And that's indicating --
7 that's what makes this arginine vasopressin is the existence
8 of that Arg amino acid there. If this was lysine vasopressin,
9 for example, that would be an Lys instead of an Arg.

10 We also see it earlier in the patent where it says it's
11 illustrated below sequence ID number 1 and they give the
12 chemical structure. And, again, at the bottom we put a box on
13 slide 39 around the Arg. And, again, that's indicating that
14 it's arginine vasopressin. Again, if that was lysine
15 vasopressin, that would be an Lys that would be shown there.

16 And, again, the table that we looked at earlier all
17 reference arginine vasopressin. So table 3, it specifically
18 says, arginine vasopressin AVP. That's arginine vasopressin.
19 Again, in the chemical structure that appears again later,
20 sequence ID number 1, it has the Arg instead of the Lys
21 indicating that it's arginine vasopressin. It's also in table
22 1. So it's throughout the specification they made clear that
23 it's arginine vasopressin.

24 The sequence listing also makes clear it's
25 synthetically derived vasopressin. So if we go to sequence ID

1 number 1, it says on slide 43, where we include the sequence
2 listing, Organism: Artificial sequence. Other information:
3 Description of artificial sequence: Synthetic peptide.

4 So it's making clear that this is something that's
5 synthetically derived as opposed to something that is derived
6 from natural origins.

7 So there's no dispute that vasopressin occurs naturally
8 in the human body. And there's a portion of the specification
9 in the background section where they're just explaining how it
10 works in the body and it notes that that's the case. But when
11 they're talking about the compound that they're claiming, when
12 they're talking about the claimed invention and what's going
13 into the various compositions that they're claiming, they do
14 so by reference to the sequence listing, and the sequence
15 listing makes clear that it's synthetic arginine vasopressin.

16 On slide 44 we again have a reference where they're
17 specifically referring to synthetic. It's talking about how
18 you can formulate this into a composition. And it's
19 consistent with the USP for vasopressin which makes clear that
20 it's referring -- when it's referring to vasopressin for
21 purposes of USP vasopressin, that it's prepared synthetically
22 and it's arginine vasopressin. So their arguments are it
23 doesn't -- there's no expressed definition that says
24 vasopressin -- by the term vasopressin we mean X, but it
25 doesn't have to be -- there's no rigid formulas that's

1 required. If you make clear in the specification that's what
2 you're referring to, then that's -- you can provide your own
3 definition that way.

4 And, you know, their argument is that they say the word
5 "synthetic" only appears twice in the specification. That's
6 not true. And, most importantly, it appears specifically in
7 the sequence ID listing so that makes clear that that is
8 synthetic vasopressin.

9 MS. LYDIGSEN: Good morning, Your Honor.

10 THE COURT: Good morning.

11 So what happened in Delaware with this term?

12 MS. LYDIGSEN: There was no dispute in Delaware.
13 Eagle agreed to Par's proposal in Delaware, and we think the
14 reason for that is because -- the reason that we're fighting
15 about this, which only came to light recently, is that there
16 is a prior art Lithuanian patent that discloses a formulation
17 that uses naturally occurring arginine vasopressin. So we
18 believe that plaintiffs sought this construction in Delaware,
19 knowing about that reference, and got Eagle's agreement. It
20 doesn't explicitly spell out in their construction that
21 they're trying to limit it to synthetic. That came out in the
22 meet and confer process in this case.

23 So we think that that's why they're trying to seek this
24 construction to exclude synthetic arginine vasopressin and try
25 to distinguish themselves from that prior art reference and we

1 don't think that that's proper.

2 In general we agree with Par about what vasopressin's
3 ordinary meaning is. It's the active pharmaceutical
4 ingredient in both Par's Vasostrict product and Sandoz's
5 generic product that are subject to its ANDA. And the term is
6 used in the scientific literature to refer to two different
7 forms of vasopressin, which are shown on this slide. The
8 arginine vasopressin, which has an arginine vasopressin at the
9 eighth amino acid sequence. You see those complicated
10 molecules on the right. Oftentimes with peptides, we instead
11 describe them in terms of the sequences, which is a little bit
12 simpler, and then the only difference we see between that and
13 the vasopressin that occurs in some animals is that there's a
14 lysine at the 8th position. Both are vasoconstrictors and
15 they occur naturally in animals but can be synthesized.

16 Mr. Rhoad went through what the various limitations
17 are. I spelled them out here. We think the most important
18 one and the crux of the parties' dispute is actually with
19 respect to that first limitation that they're trying to read
20 into the claim, which is whether or not the vasopressin is
21 synthetic.

22 The second thing that they attempt to read into the
23 term vasopressin is that it has to be limited to sequence ID
24 number 1. We don't think that's as material to the parties'
25 dispute, but we also think that that is improper in this case.

1 And then third Par --

2 THE COURT: Why? What would that improper?

3 MS. LYDIGSEN: Let me -- there's a couple reasons.

4 So when you look at the claim itself, this is just
5 exemplary. This is the '239 patent. Vasopressin is used in
6 all the claims. It doesn't list the sequence ID there, right?
7 It just refers to vasopressin generically. Then if you go to
8 the dependent claimants, frequently they do require specific
9 ID numbers 2, 3, 4. So when Par intended to limit the claims
10 to a specific sequence ID, they did so. They did not do that
11 with vasopressin. Instead they used the term broadly.
12 There's a reason for this. The regulations that govern how
13 patent claims are drafted in this area in peptides require
14 that if you're going to claim a specific sequence ID number,
15 you need to include that magic language in your claim sequence
16 ID. It's not enough, according to the regulations, which is
17 reproduced here at 37 CFR section 1.821, to just refer back to
18 something with specification. You need to actually state the
19 sequence ID number. They did not do that here. So it's
20 improper to read that into the claim.

21 I'd like to turn back to the first issue, though, which
22 is whether or not vasopressin should be limited to synthetic
23 vasopressin. Before I do that, turn to -- their construction
24 refers to columns 25 and 26 of the patent specification, and
25 they draw out arginine synthetic, sequence ID number 1, from

1 these two columns, which are reproduced on this slide. What's
2 missing in those two columns and the subsequent sequence ID
3 number 1 listing is anything that says vasopressin means,
4 vasopressin is defined as, anything that would qualify as
5 lexicography, a clear definition. That's what's needed under
6 patent law under the federal circuit law in order to define a
7 term, is something narrower than its ordinary meaning, which
8 in this case would cover both natural and synthetic
9 vasopressin, lysine, arginine, and for some variation of
10 sequence ID.

11 The other thing that's problematic about the reliance
12 on reading these limitations in from columns 25 and 26 is that
13 what it says in the specification itself, far from having
14 limiting language, that these passages actually begin with the
15 title "embodiment" and state that the following
16 non-embodiments provide illustrative examples of the
17 invention, but do not limit the scope of the invention.

18 And so rather than attempting to limit the scope of
19 vasopressin to specific features -- synthetic, arginine,
20 sequence ID number 1 -- the specification says just the
21 opposite, that it's a nonlimiting embodiment.

22 The specification with respect to -- is also clear that
23 more than synthetic vasopressin is encompassed. This is early
24 on in the specification. It states that vasopressin is
25 synthesized as a prohormone in neurosecretory cells of the

1 hypothalamus. That's a part of the brain. So in other words,
2 the specification states that vasopressin is made by the
3 brain. It's made naturally. They're very -- the patent
4 specification does not state it needs to be synthetic or is
5 necessarily synthetic.

6 They rely on several passages that describe synthesis
7 of arginine vasopressin. This is the primary one. It says,
8 vasopressin is a polypeptide hormone that causes contraction
9 of the vascular and other smooth muscles and antidiuresis,
10 which can be formulated as a sterile aqueous solution of
11 synthetic arginine vasopressin. The key thing there is it
12 says it can be formulated, not that it is formulated or
13 exclusively formulated.

14 Other places in the patent specification state just the
15 opposite, that it's naturally occurring. This is also
16 consistent with the extrinsic evidence that vasopressin is not
17 limited to synthetic vasopressin. I reproduced an excerpt
18 from the USP, the US Pharmacopeia, which is a compendium with
19 -- that's used by folks in the field, medical field, and it's
20 from the same year as the section that they rely on. This is
21 for vasopressin injection, and it specifically states that
22 vasopressin injection includes products of animal origin. And
23 then in that second highlighted passage, there's a
24 parenthetical that says it's animal or synthetic. In other
25 words, it can be naturally occurring or synthetic. And so a

1 person with ordinary skill in the art would understand based
2 on the specification and their knowledge of the field,
3 including the USP, that vasopressin is not necessarily
4 synthetic vasopressin.

5 I'd like to briefly turn to the third limitation they
6 attempt to read into the claim, which is that vasopressin
7 should be limited to arginine vasopressin. Again, the
8 specification says that the vasopressin can be formulated as
9 arginine vasopressin, not that it necessarily is.

10 And if we look at the extrinsic evidence, this comes
11 from another version of the USP, here it says vasopressin
12 injection expressly lists both the sequence and name for
13 arginine vasopressin as well as lysine vasopressin under the
14 same heading for vasopressin injection.

15 And so lysine vasopressin would be encompassed within a
16 person of ordinary skill's understanding of the term
17 vasopressin.

18 And then finally -- this is a prior art article from
19 Treschan. And here the author describes that vasopressin
20 should be specifically called arginine vasopressin, AVP, to
21 distinguish it from analogs. And so when the person of
22 ordinary skill in the art wanted to refer to specifically
23 arginine vasopressin, they did so. They would describe it as
24 arginine vasopressin. The claims do not do that here, and
25 there's nothing in the patent specification that specifically

1 would qualify as lexicography that might limit those -- the
2 ordinary meaning of the claims.

3 THE COURT: Thank you.

4 Counsel.

5 MR. RHOAD: Your Honor, I just want to respond quickly
6 to three of the points that counsel raised.

7 The first one relates to the regulation from the CFR,
8 which they have on their page 58, slide 58. And the
9 regulation specifically contemplates that the identification
10 of the sequence ID number can occur in the specification or
11 the claims. It says, Reference must be made to the sequence
12 by use of the sequence identifier preceded by sequence ID
13 number in the text of the description or claim.

14 So their assertion that somehow the fact that it
15 doesn't say sequence ID number 1 in the claims somehow
16 violates this regulation is just wrong. And that's the whole
17 point of including a sequence ID number listing and
18 identifying vasopressin by way of sequence ID number 1, was to
19 make clear that that's what they're referring to.

20 The second thing I wanted to talk about was their
21 reference to the embodiments, and they cited in their slide 52
22 a reference -- in column 25 -- to being nonlimiting
23 embodiments. And they say somehow that precedes the sequence
24 ID listings as if the sequence ID numbers are somehow part of
25 the embodiments. That's just a separate -- the portion they

1 cite is not relevant to the sequence ID listings which are
2 simply at the end of the patent they included sequence
3 listings. So that portion of the specification they cited has
4 nothing to do with the sequence listings.

5 Finally, on the USP, they cite the references to
6 labeling in the USP and labeling it as natural or synthetic.
7 And that just refers to the fact that the USP makes clear --
8 USP vasopressin is synthetic arginine vasopressin. And it
9 makes clear that if you're going to use some other form of
10 vasopressin, you have to make it clear on the label so
11 nobody's confused. That simply confirms our assertion that
12 everybody understands when you're talking about vasopressin,
13 you're talking about synthetic arginine vasopressin in
14 accordance with the USP. They cite an earlier version that
15 included within USP vasopressin lysine vasopressin, but that
16 had changed by the time of the claimed invention. So the
17 relevant inquiry is at the time of the claimed invention. By
18 that time the USP had dropped lysine and everybody understood
19 USP vasopressin is synthetic arginine vasopressin.

20 MS. LYDIGSEN: I don't think I have much more to say.
21 We stand by our reading of the regulation which states it has
22 to refer to the specific sequence ID number. And with respect
23 to the USP, the portion that was cited initially in our slides
24 comes from the same edition as theirs. Nothing changed. That
25 was current as of 2015 referencing both animal and synthetic

1 vasopressin. Thank you.

2 THE COURT: Number 3.

3 MR. RHOAD: Your Honor, the next term that we have
4 identified for construction is the "consists essentially of"
5 term. And it's one of the transitional phrases that's
6 recognized for use in patent claims. It's kind of unusual.
7 It's not used a lot, but it has a clear and ordinary meaning
8 which is that, you know it's between comprising which allows
9 you to have all the things that were cited plus anything else
10 and "consists of" which says you can only have the recited
11 ingredients. And sort of in between those two, you have to
12 have the recited ingredients, but you can also have other ones
13 so long as they don't materially affect the basic and novel
14 characteristics of the claim. We think it's that ordinary
15 meaning that should apply.

16 Just for -- kind of orient ourselves, this transitional
17 phrase appears in only one of the patents, the '478 patent and
18 claim 1 of the '478 patent. So this term is limited in terms
19 of its impact to that one particular patent and the claims
20 that are found in here.

21 As I said, you know, this term has it's well understood
22 meaning and so the recited components of the unit dosage form
23 in claim 1 are three things. You have the vasopressin or a
24 pharmaceutically acceptable salt thereof, which plays into
25 what we'll talk about in a minute, and has an acetate buffer

1 and water. So under this transitional phrase you have to have
2 those three things, and you can include other ingredients so
3 long as they don't materially affect the basic and novel
4 properties of the invention.

5 So when you use this type of transitional phrase, the
6 federal circuit has told us it really raises two questions for
7 the Court to consider in terms of doing an infringement or
8 validity analysis. The first is what are the basic and novel
9 characteristics of the claimed inventions. So that's sort of
10 the first question. The second question is does the
11 particular unrecited ingredient that's either in the accused
12 product or the prior art formulation at issue, does it
13 materially affect those?

14 So the first question, what are the basic and novel
15 properties, that really is a claim construction question
16 regarding what's the scope of the claim, what are those basic
17 and novel characteristics?

18 That second question, though, is one -- it's an
19 infringement question for the fact-finder to determine. Okay.
20 You know, you have this particular additional unrecited
21 element. Is that something that materially affects the basic
22 and novel characteristics and properties of the claimed
23 invention?

24 So the issue here is we just say ordinary meaning.
25 Sandoz argues that this phrase is indefinite. They want to

1 invalidate the claim saying it's indefinite, saying people of
2 ordinary skill have no idea what you're talking about. They
3 can't understand the scope of this claim. It's indefinite.

4 So the first issue is what's the standard for
5 indefiniteness? Since they're trying to invalidate the claim
6 as indefinite, it's different than the normal claim
7 construction.

8 THE COURT: When should that be done, here or later?

9 MR. RHOAD: In our view it would make more sense to
10 do it later when the Court has full expert testimony. This is
11 going to be a bench trial so we don't have to worry about jury
12 confusion or anything like that.

13 THE COURT: How about that case that was cited in
14 their brief, the recent federal circuit case?

15 MR. RHOAD: So that case says it's part of claim
16 construction and we're not disputing that. It's up to -- if
17 Your Honor wishes to do it now, we're happy for Your Honor to
18 do this question of this first, what are the basic and novel
19 characteristics of the claim? Courts -- district courts have
20 discretion to manage their docket any way they want. You
21 don't even have to hold a Markman hearing. You don't have to
22 do claim construction before trial. You can do it whenever
23 you want. So it's up to Your Honor's discretion when you
24 believe is the best time. We're not saying you can't do it
25 now or you have to do it later.

1 THE COURT: Do I have everything I need to do it now?

2 MR. RHOAD: I think you do. I think you can make --
3 answer the first question, what are the basic and novel
4 characteristics? I think you have what's needed. I think
5 it's clear from the specification and the prosecution history
6 and the intrinsic evidence what those properties are.

7 So I think you have what you need at the moment.
8 Obviously after trial or at some point in the trial you'll
9 have more expert testimony. You'll have a better
10 understanding of the compositions at issue and you might be a
11 little bit more informed in making a decision at that point.
12 But I think you have enough to make the call right now.

13 THE COURT: All right.

14 MR. RHOAD: But I think the important thing is from
15 burden of proof and the standards applicable here, we're not
16 talking about normal claim construction where -- from a --
17 where you're deciding something, you know, based upon your
18 view of the evidence and intrinsic evidence and whatnot.

19 THE COURT: What is the standard to do that?

20 MR. RHOAD: The standard, first of all, is -- for
21 indefiniteness, standards would have to prove that the claims
22 failed to inform those of skill in the art about the scope of
23 the invention with reasonable certainty. So that's what we
24 have from the Supreme Court *Nautilus* case. That's the general
25 standard for indefiniteness. But what's clear is that this is

1 an invalidity defense. So like all invalidity defenses in
2 accordance with the *Microsoft* Supreme Court case, Sandoz has
3 the burden of proving indefiniteness by clear and convincing
4 evidence. That's a heavy burden of persuasion and the law is
5 also clear in terms of the standards for indefiniteness. The
6 fact that there's some imprecision involved doesn't mean that
7 it's indefinite. You can use relative terms. And the fact
8 that there is some imprecision involved doesn't mean that a
9 claim is indefinite.

10 And here, in our view, Sandoz, clearly failed to meet
11 their burden. The relevant perspective is a person of
12 ordinary skill in the art -- would the claims inform a person
13 of ordinary skill in the art about the scope of the claims
14 with -- to a reasonable degree of certainty, and they have no
15 expert evidence on this point. They have no expert coming in
16 here saying I can't understand this claim. It doesn't tell me
17 about the scope of this claim with reasonable certainty.
18 There is no evidence from an expert to that point. They're
19 relying entirely on lawyer arguments.

20 They cite no case in which a patent was invalidated on
21 indefiniteness without some form of expert testimony. The
22 principal case they relied on in their reply brief is this
23 recent federal circuit case, and that explicitly relied on
24 expert evidence and experts who came in and said we can't
25 understand -- we can't determine the scope of these claims for

1 X, Y and Z reasons, and the courts found that persuasive and
2 found invalidity on the basis of that expert testimony. So in
3 our view, they have failed as a matter of law by not providing
4 the requisite evidence to establish clear and convincing
5 evidence of invalidity.

6 But let's take a look at -- so the first question under
7 this recent federal circuit case is what are the basic and
8 novel properties of the claimed invention?

9 When we talk about that in the context case, the
10 claimed invention is clearly directed to vasopressin
11 compositions that are intravenously administered to patients
12 to treat hypotension. It's a pharmaceutical product. It's
13 used to treat patients for a particular condition that's
14 expressly recited in the claims in this instance of this
15 particular patent.

16 You know, so the patentees didn't claim to be the first
17 people ever to invent vasopressin, but what they did say is
18 they described the problems that existed with the existing
19 vasopressin formulations at the time. And what they said is,
20 hey, vasopressin degrades in aqueous solutions. So you put it
21 in water and it starts to degrade and the degradation gets
22 worse over time. So that's a problem when you're formulating
23 these kinds of compositions. And they said the then current
24 formulations had poor long-term stability. And then in the
25 rest of the spec, they described a bunch of experiments they

1 did, testing they did to various things and what can impact
2 stability and the amount of vasopressin. And during the
3 prosecution history there was back and forth about it and they
4 pointed to the stability of the product at the particular pH
5 that they claimed and said that's what differentiates us.
6 That's what makes us novel and patentable over the prior art.
7 And they expressly -- on slide 56 we have a statement
8 by them where they specifically describe the advantages that
9 they provide. It says they provide advantages in stability,
10 administration, and efficacy as well as formulation viscosity.
11 And so our proposal -- so we set forth a position as to what
12 we assert are the basic and novel characteristics of the
13 claimed invention. Sandoz has not offered any list of what
14 they are. They just say they can't possibly know what it is.
15 And so on slide 57 we set forth the four things that we say
16 together comprised the basic and novel characteristics.
17 Stability, that addresses -- that relates to the problem they
18 identified and the advantage they identified in stability.
19 It's also pharmaceutical acceptability. This has to be a
20 product that's suitable for use as a pharmaceutical product.
21 Effectiveness in treating hypotension. That's what this is
22 about. It's treating patients who have -- hypotension is low
23 blood pressure. So what happens, people come to the hospital,
24 they're in septic shock, really low blood pressure, it needs
25 to be raised. That's part of what these inventions are about.

1 Then suitability for intravenous injection in particular.

2 That's what they're talking about. So we identified those
3 four things.

4 Sandoz makes essentially three arguments. The
5 intrinsic evidence doesn't identify those things, these
6 properties, and I'll touch base on that. That's just not the
7 case. It's not true. We'll talk about that in a minute.
8 They say the properties are not novel. That's an invalidity
9 argument that these are invalid under '102 and '103, that
10 these aren't novel. That's for another day. That's when --
11 there's no expert here saying this isn't novel stuff. In
12 terms of whether or not they're novel, that's for another day.

13 And I say the properties cannot be understood with
14 reasonable certainty. And that really goes to the second
15 question when you're talking about whether something
16 materially affects one of these properties. And that's a time
17 for infringement and invalidity. That's not something, at
18 least in the circumstances of this case, that we say can be
19 addressed right now.

20 So in terms of that first question, the first argument,
21 what are the properties, you know, they have this, I find it
22 somewhat remarkable, statement that we quote on page 59. They
23 say, Only one of the four properties identified by Par even
24 appears in this sentence -- stability. And they're referring
25 to a sentence we had on slide 56 where it's describing the

1 advantages. Okay. And they say, Only one of them appears in
2 the advantages. I'm at a loss to understand their argument
3 because it mentions stability, but it also means that it's
4 pharmaceutically acceptability. So on slide 60 the sentence
5 says, Embodiments of pharmaceutical formulations that provide
6 advantages. So it's clearly referring to pharmaceutical
7 products. Products that have to be acceptable for use in a
8 pharmaceutical product.

9 The sentence next we identify was effectiveness in
10 treating hypotension. Specifically one of the advantages
11 referred to is efficacy. Efficacy is effectiveness and
12 hypotension is mentioned specifically in the claims. So the
13 efficacy we're talking about for purposes of this claim is
14 hypotension.

15 Suitability for intravenous injection. It specifically
16 references in that sentence "administration." That's the form
17 of administration that they're talking about, intravenous
18 injections. So all four are expressly referenced in that
19 sentence. The intrinsic evidence makes clear that it's those
20 four. It's also provided elsewhere throughout the
21 specification.

22 Stability, as I noted, is described as the problem,
23 described as an advantage, and the -- the specification
24 includes extensive discussion of that and the prosecution
25 history is what made it patentable.

1 Pharmaceutical acceptability. Again, these are
2 pharmaceutical products. They have to be -- acceptable for
3 use in pharmaceutical products.

4 Effectiveness in treating hypotension. Again, that's
5 right in the claims.

6 Intravenous injection. There's extensive discussion of
7 diluting intravenous injection. That's the form of
8 administration.

9 Now -- and then -- so that's the first argument that's
10 throughout the intrinsic evidence. We believe it's clearly
11 identified.

12 The second argument about novelty, there's no evidence
13 it's not novel. There's no expert out here, and this isn't
14 the right time to decide that. We believe they are novel and
15 the patent office found that they were novel.

16 The final argument is that the properties themselves
17 are somehow indefinite. That really goes to the second
18 question whether or not if you add something, it would have a
19 material effect on these properties. They submitted no expert
20 evidence on that issue at all, and there's no basis for the
21 Court to conclude on this record that there's anything
22 indefinite about those four things. If you think about it
23 practically, it seems clear and obvious to me that a person of
24 ordinary skill in the art would understand this.

25 Pharmaceutical acceptability. If I add something, that means

1 you can't inject it into a human. The FDA includes a list of
2 ingredients that are acceptable in pharmaceutical products.
3 Well, if you add something that's going to be toxic to
4 somebody so it's no longer pharmaceutically acceptable, that's
5 materially affecting the basic novelties of -- and properties of
6 this -- of this product. It has to be pharmaceutically
7 acceptable. And experts would know whether things affect
8 suitability for that.

9 Effectiveness. It's efficacy in treating hypotension.
10 Again, experts can figure out whether something materially
11 affects its efficacy. And that should be no problem.

12 Suitability for intravenous injection. Again, if you
13 add something that makes this a gel or a solid, it can no
14 longer be injected. That's clearly materially affecting it.
15 It seems readily apparent. Stability, you add something that
16 adversely affects the stability, it's going to be known. They
17 simply can't prove that these claims are indefinite.

18 THE COURT: Do you agree with counsel regarding the
19 standard that the Court needs to employ at this juncture and
20 who has the burden?

21 MS. LYDIGSEN: Yes. Sandoz has the burden of proof
22 by clear and convincing evidence. We believe that exists here
23 based on the specification itself, however, and there's no
24 need for expert testimony. Their own patent specification
25 makes -- fails to disclose the basic and novel properties with

1 sufficient clarity for a person of ordinary skill to identify
2 them.

3 THE COURT: Who tells me that?

4 MS. LYDIGSEN: Who tells you that?

5 THE COURT: Yes. You?

6 MS. LYDIGSEN: It should be apparent from the
7 specification. It should be reading the specification.
8 There's no reason why we need an expert mouthpiece to read the
9 patent specification.

10 THE COURT: To say what a POSA would interpret this
11 or how a POSA would read that, I don't need an expert for
12 that?

13 MS. LYDIGSEN: Not for identification of the basic
14 and novel properties. You should be able to read the patented
15 claims and specification and pick out those properties with
16 some level of certainty. It should not take a Ph.D. degree to
17 be able to determine what those properties are.

18 Here's the parties' construction side by side. Par
19 says that the term "consists essentially" should be given its
20 ordinary meaning and then has a long parenthetical with those
21 four properties. Sandoz's position is that the term is
22 indefinite as used in claim 1 of the '478 patent, which would
23 also render the dependent claims, the 2 through 11, indefinite
24 and knock out that entire patent.

25 This is just consists -- Mr. Rhoad already went through

1 some of it. It's a transitional phrase that appears after the
2 preamble of the claim and before the body which lists the
3 elements. Here the preamble recites a method of using a unit
4 dosage form and then it uses the transition "consists
5 essentially of" and there's elements A, B, and C.

6 As Mr. Rhoad mentioned, there are several different
7 types of transitional phrases. I've listed the three common
8 ones here in the description from the MPEP about them. The
9 open transitional phrase, which Your Honor's probably seen
10 before, is comprising. And so with a comprising transition,
11 the claim would cover anything that has the recited elements
12 and additional elements. If you looked at claim 1, if it had
13 a comprising transition that consists essentially of, the unit
14 dosage form could include elements A, B, and C and anything
15 else.

16 But Par didn't claim it that way. They chose a more
17 closed transitional phrase, "consists essentially of," and
18 that limits the scope of the claim to the specific materials
19 or steps and those that do not materially affect the basic and
20 novel characteristics of the claimed invention. That's not
21 only from the MPEP but from the case law. The *HZNP* decision
22 from the federal circuit last fall that Your Honor cited
23 quotes to earlier cases that recited that the phrase
24 "consisting essentially of" permits inclusion of components
25 not listed in the claim, provided they do not materially

1 affect the basic and novel properties of the invention.

2 And that case provided some very helpful guidance on
3 how to deal with "consists essentially of" at the claim
4 construction stage. We generally agree with Par there's a
5 two-step inquiry. Number one, you have to be able to identify
6 the basic and novel properties that go with that "consists
7 essentially of" transition. And then once those properties
8 are identified, there has to be an assessment of whether or
9 not they're definite.

10 Under 35 U.S.C. Section 112, paragraph B, the basic and
11 novel properties must be sufficiently definite to inform with
12 reasonable certainty a person of ordinary skill of their scope
13 within the context of invention.

14 So looking at -- I want to direct Your Honor's
15 attention to the bottom five lines there in Par's
16 construction. That's where the -- the properties that they
17 contend that the basic and novel properties are laid out.
18 Stability, pharmaceutical acceptability, effectiveness in
19 treating hypotension and suitability for intravenous
20 injection. And this is the passage of the patent
21 specification that Par pointed to at column 15 starting at
22 line 26 that they say lists the properties. It's featured
23 heavily in Mr. Rhoad's presentation. Here it is side by side
24 with the four properties that they've identified.

25 Mr. Rhoad for the first time is now saying that he can

1 carve out -- stability is the only one that appears there
2 verbatim. He says, well, you would actually -- a person of
3 ordinary skill would actually understand administration of
4 efficacy to -- and breach the three other three properties
5 that he lists, but for reasons that are unexplained still,
6 they would ignore that fourth property that's listed in the
7 patent specification, modulation of formulation of viscosity.

8 I think that that position is a little bit problematic
9 because their own patent -- it's very vaguely stated at column
10 15 that says administration and efficacy, not pharmaceutical
11 acceptability, not effectiveness in treating hypotension, not
12 suitability for intravenous injection. And anybody, a person
13 of ordinary skill or otherwise, reading a patent specification
14 would understand that they don't specifically recite only
15 effectiveness in treating hypotension. If you go to column --

16 THE COURT: Who tells me that? I mean, I'm certainly
17 not a POSA, and don't I need somebody to say what a POSA would
18 say or how a POSA would read that? And isn't that your burden
19 to prove that?

20 MS. LYDIGSEN: But it's in the patent specification,
21 and here it's at column 4 of the '478 patent. When you're
22 talking about -- they say it's effectiveness in treating
23 hypotension and that the person of ordinary skill would read
24 "efficacy" to mean that. But if you --

25 THE COURT: Who is the person of ordinary skill? Me?

1 MS. LYDIGSEN: It's not you, Your Honor, but this is
2 about reading the patent specification, and this is not
3 something that would require a higher level of ordinary skill
4 to pick out what they're claiming in their patent
5 specification what the basic and novel properties are.

6 THE COURT: Do you agree with that?

7 MR. RHOAD: Your Honor, I think it requires -- to the
8 extent it requires expert evidence, to the extent there's any
9 ambiguity or that the specification needs it. And, in fact,
10 we're talking about hypotension. It's in the claim itself,
11 so --

12 THE COURT: Okay. Counsel, I cut you off. I'm
13 sorry.

14 MS. LYDIGSEN: We have a collection of cases that are
15 cited in our opening brief at page 18 where the basic and
16 novel property identification is done based on the patent
17 specification. And that was also what we've done on the *HZNP*
18 decision. I'm going to skip out of order here for a minute
19 and show you what the court relied on in *HZNP* to identify the
20 basic and novel properties. This is what the federal -- the
21 federal circuit found that they were sufficiently identified
22 there and they looked at the patent specification. It was not
23 based on expert testimony. The judges looked at the patent
24 specification. In that case they were clearly spelled out.
25 There were five headings, one for each property that was

1 verbatim what the plaintiff contended those properties were in
2 that case. And under each heading there was a description of
3 the specifics of that property.

4 That is not the case here. What we have is a -- one
5 sentence at column 15 that's very vague that describes
6 administration, efficacy. And then there are other portions
7 of the patent specification that describe different -- not
8 just hypotension but treating other diseases. That's at
9 column 4, line 7. There's a long list of other diseases. And
10 then with respect to administration, they say that, well,
11 administration would need IV administration. Of course a
12 person of ordinary skill would know that. But their patent
13 specification at column 7, line 28 says pharmaceutical
14 composition can be administered in therapeutically effective
15 amounts. For example, intravenous, subcutaneous,
16 intermuscular, transdermal or parenteral administration.

17 You don't need to be a person of skill in the art to
18 understand that their patent specification is vague as to what
19 the basic and novel properties are.

20 For this type of claim, what they're trying to use is a
21 semiclosed transitional phrase, it's their -- I think that's
22 their burden to say something in the patent specification that
23 helps provide a flag post for anyone reading it to understand
24 what those properties are and what the claim means.

25 The other reason why I don't believe a person of

1 ordinary skill would identify these properties in particular
2 from column 15 is the fact that they're not novel. This slide
3 shows one particular prior art reference from Buck and the
4 four properties that Par identifies side by side. And with
5 respect to stability, Buck discusses the fact that there was
6 prior art, vasopressin formulations are used, and the issue
7 wasn't stability with those but whether or not they would be
8 stable when co-administered with other drugs. There's been
9 some success with it, but it hasn't been formally studied yet.

10 With respect to Par's properties two and three which
11 relate to pharmaceutical acceptability and effectiveness in
12 treating hypotension, Buck reports a number of clinical
13 studies where vasopressin was used to treat hypotension and
14 was pharmaceutically acceptable.

15 And then finally with respect to the suitability for
16 intravenous administration, Buck said that was done in the
17 prior art too. So we had a patent specification with some
18 vague listing of properties that aren't spelled out as basic
19 and novel properties. Par wants you to take three of those
20 four that are listed in column 15 and extrapolate from two of
21 them to turn into three properties using other parts of the
22 patent specification in the claims and ignore the fact that a
23 person of ordinary skill would recognize that none of those
24 properties were new. What are the novel properties? The
25 specification does not spell them out for us.

1 But even if you can identify the basic and novel
2 properties with sufficient specificity, Par has a second
3 problem and that's at step two, whether or not those
4 properties are sufficiently definite. And, again,
5 specification itself makes it clear that they're not definite
6 here.

7 This is the standard from -- for definiteness that was
8 spelled out in the *HZNP* decision which also involved an
9 evaluation of "consists essentially of" on a particular
10 patent. There the court said, It follows that those basic and
11 novel properties, when read in light of the specification and
12 the prosecution history, must provide objective boundaries for
13 those of skill in the art. The basic and novel properties
14 must be sufficiently definite so as to inform with reasonable
15 certainty a person of ordinary skill of their scope within the
16 context of the invention.

17 So there's that passage from *HZNP* side by side with the
18 four properties that Par spells out. Now, in *HZNP* the federal
19 circuit only went through this analysis for one of the
20 properties there because they found that property was
21 indefinite. So even if one property is indefinite, the claim
22 is indefinite.

23 So I'm just going focus on stability because that's the
24 only property that actually appears verbatim in column 15.
25 And even if that was sufficiently identified, Par has a

1 problem here because their own patent specification indicates
2 that that property is not sufficiently definite for a person
3 of ordinary skill in the art to understand the scope of the
4 claim.

5 The specification here describes numerous measures of
6 stability, and this slide shows one of those which is half
7 life. And rather than defining an objective boundary that
8 would help a person of ordinary skill understand what level of
9 stability they believe is novel and what are the basic and
10 novel properties of the invention, this passage describes half
11 lives of one to 1,000 percent at five percent increments for
12 the first 100 percent and then 100 percent increments after
13 that.

14 Then half lives of one to 1,000 percent of another
15 formulation measured at another temperature at five to 100
16 percent increments. Half lives of one hour to one week at one
17 hour increments for the first day and six- to 12-hour
18 increments thereafter. Instead of claiming something narrow
19 and giving some boundaries, some benchmarks for what makes a
20 novel level of stability, the claim -- the patent
21 specification purports the invention covers every level of
22 stability. But if there's more, the patent specification also
23 describes virtually every level of decomposition.

24 This slide shows that the patent drafters stated that
25 the inventions include 1 to 1,000 percent decomposition of

1 another formulation at five percent increments for the first
2 100 percent and 100 percent thereafter. Temperature for
3 testing zero to 75 degrees celsius at one degree increments
4 and .1 degree increments for 20 to 25 degrees celsius
5 specifically. Again, no benchmarks.

6 Goes on, virtually every level of purity is described
7 in the patent specification. They claim the inventions cover
8 1 to 99 percent purity of vasopressin at .1 percent increment.
9 Virtually every level of sequence similarity with sequence ID
10 number 1 is also covered. The same story applies there with
11 these tiny increments between different percentages and
12 virtually every mix of other peptides, ratios from 1,000 to 1
13 to 10 to 1. And also with percentage measurements from .1 to
14 100 percent at 1 percent increments. You don't need to be a
15 person of ordinary skill in the art to read the specification
16 and know that there's no benchmark here. There's no
17 boundaries. They're purporting to cover every possible level
18 of stability and yet saying it's a basic and novel property.

19 If this were not enough, they have a second problem.
20 And this slide comes from an excerpt in the '223 patent which
21 is related. And there it describes how the stability of the
22 vasopressin formulation would vary depending on the
23 temperature that -- in which it's stored. Here, it purports
24 that the amount of impurities observed in the sample stored at
25 25 degrees celsius and 60 percent relative humidity after 24

1 months exceeded 13 percent in some samples where the amount of
2 impurities observed in the samples stored at five degrees
3 celsius do not exceed three percent after 24 months. So you
4 can get a ten percent variation depending on temperature. And
5 there's no indication in the patent specification as to how
6 this should be tested.

7 That was enough in *HZNP* to invalidate the claims there.
8 The drying time -- drying time was identified as the basic and
9 novel property, and based on the specification the Court found
10 that because there were different tests for drying time that
11 produced different results that that particular basic and
12 novel property was indefinite.

13 Now, Par's counsel says that *HZNP* is hinged on expert
14 testimony. That was not the case. There were expert
15 declarations put in at the Markman stage, but if you look at
16 the federal circuit decision, the federal circuit relied on
17 the patent specification alone. That was what they weighed in
18 determining that the claims were invalid as indefinite. And
19 here they have multiple problems both with step one and two,
20 which makes it an even stronger case for invalidity at the
21 claim construction stage.

22 THE COURT: Okay. Thank you.

23 MR. RHOAD: Your Honor, just very briefly. You know,
24 I think Your Honor hit the nail on the head asking questions
25 about who's deciding this, you know, is it you or is it an

1 expert who's telling you this? There's no dispute that a
2 determination is going to be made based upon the intrinsic
3 evidence. But it's how a person of ordinary skill in the art
4 reads the intrinsic evidence, not how a lawyer or a judge
5 reads that intrinsic evidence. It's what would be understood
6 by a person of ordinary of skill in the art.

7 And so, you know, they say hypotension is not part of
8 it because it describes treatment of a variety of different
9 conditions. Well, claim 1 that we're talking about
10 specifically refers to -- in the last line -- wherein the
11 person is hypotensive, it's very clear. Let them come in with
12 an expert who says, I don't understand this has to be
13 effective for treating hypotension. There's no expert saying
14 that because it's just not true.

15 They pointed out various excerpts from throughout the
16 specification regarding stability. But there's no expert to
17 tell Your Honor that in light of those they're somehow
18 confused about what's meant by stability. And I think their
19 presentation highlights the importance of that ex -- having an
20 expert come talk to Your Honor about that because they
21 completely ignore the prosecution history where they --
22 inventors submitted -- did testing on stability, submitted it,
23 explained to the patent office why they believed this had --
24 the particulars of this claim had advantages with respect to
25 stability and why that made it patentable over the prior art.

1 They need to come in with an expert and say notwithstanding
2 all of that prosecution history and what was done there, I
3 can't understand this claim. I don't know what they're
4 talking about with stability. Let an expert come and tell the
5 Court that. They're asking you to interpret, pick out bits
6 and pieces from the specification and reach a conclusion about
7 whether or not a person of ordinary skill would be able to
8 understand the claim. That's just improper claim
9 construction, and their evidence is just woefully short of
10 meeting the standard of proof of clear and convincing
11 evidence.

12 On the notion of temperature, well, it's got to be --
13 there's no dispute that temperature has an effect on
14 stability, but when you're comparing two formulations it's got
15 to be apples to apples comparisons. And an expert would know
16 that and an expert would understand that and would tell the
17 Court that. That's the kind of evidence Your Honor needs.
18 Certainly, we think it's -- that is not indefinite and that
19 will be clear, but they haven't met their burden of proof.

20 THE COURT: Counsel.

21 MR. RHOAD: I'm sorry. The point about the *HZNP*
22 case, the *HZNP* case expressly relied on expert evidence. And
23 I have a copy in my bag, not present, but I can point Your
24 Honor to specific passages. But it's very clear in the case.

25 MS. LYDIGSEN: I don't deny that the *HZNP* case in the

1 background mentions the fact that the district court looked at
2 expert declarations, but it was not relied on by the federal
3 circuit. Unless Your Honor has more questions, I have nothing
4 further.

5 THE COURT: Thank you.

6 Last but not least.

7 MS. GAGLIARDI: Good morning, Your Honor. Sharon
8 Gagliardi on behalf of plaintiffs.

9 The last term for construction is where impurities are
10 determined based on a specified HPLC method. The dispute
11 here, Par's construction is that the term should be supported
12 as plain and ordinary meaning and no construction is required
13 whereas Sandoz contends that this claim limitation is --
14 requires a step be performed in terms of -- to determine
15 impurities as part of the active infringement.

16 It's implicated in two claims, the '209 claim 11 the
17 '785 claim 2. I wanted to start with the '785 claim 2, which
18 is a composition claim. An independent claim requires --
19 recites a pharmaceutical composition and then it has
20 comprising several components of that composition. It
21 requires vasopressin. It has the fact that the composition
22 contains impurities.

23 The dependent claim, claim 2, which is the claim that
24 contains the disputed limitation, says that the impurities
25 contain a plurality of peptides, that there's a number of

1 impurities. And then it specifies a test that you can use to
2 determine whether infringement has occurred.

3 This is not a method claim. This is a composition
4 claim, and it's -- the test here is describing a test to
5 determine whether specified impurities are present.

6 The method claim, which is the method of treatment
7 claim, '209, claim 11 --

8 THE COURT: Talk to me about your widget.

9 MS. GAGLIARDI: My widget. The widget. So the
10 analogy we give is a widget that if you had a claim to a
11 widget that had a mass of 10 kilograms, right? You know, if
12 you sell a widget that has a mass of 10 kilograms, you sell
13 the widget, it has that mass. You can determine that it has
14 that mass and it infringes the claim.

15 If I specify in my dependent claim that, hey, I have a
16 widget. It has a mass, and I'm going to determine that mass
17 using a specified skill, right? The infringing act is making
18 and selling the widget that has those properties, that has a
19 mass of 10 kilograms. And the dependent claim is just
20 specifying the kind of evidence that I would need to put
21 forward to meet my burden of proof of a preponderance of the
22 evidence that it is more likely than not that it has this mass
23 using this scale.

24 It's not a step that -- it's not a method step that has
25 to be performed as part of the act of selling the product or

1 using the product. Here, the nature of the HPLC test, if you
2 understand how the test that -- I have a slide that shows what
3 HPLC is. This is high-performance liquid chromatography, and
4 this is a technique used in a chemistry lab to separate,
5 identify, and quantify components of a formulation. So here
6 you have vasopressin. As we discussed, it degrades. And you
7 have impurities present and we're trying to quantify and the
8 intention is limiting the number of impurities here that are
9 present. And so this is a technique where we can determine
10 what impurities there are and how much of them there are.

11 And so you have -- if my laser pointer would work --
12 over here you have -- you start out in the that first box,
13 number one, you have solvents that are the mobile phase, what
14 we call the mobile phase, that are mixing in with the -- a
15 pump draws them in. There are components and you put your
16 sample in there and it goes through a column and in the
17 column, the stationary phase allows you to separate out the
18 different components and identify them and then it goes into a
19 waste container. So if you're talking about a method of
20 treating a patient with hypotension and you have a person of
21 ordinary skill of how these claims are understood, if they're
22 treating a patient who is sitting in a hospital needing urgent
23 care, they're not going to be part of that method of treating
24 a patient, running to a chemistry lab, running an HPLC test
25 for 55 minutes and determining whether these impurities are

1 present. The impurities are just part of the composition
2 that's being sold.

3 So here our position is just that these are describing
4 the nature of these impurities in a test to determine whether
5 these properties are present.

6 THE COURT: Why is Sandoz's construction nonsensical?

7 MS. GAGLIARDI: I think it's nonsensical because -- I
8 don't think -- reading them in the context of how a person of
9 ordinary skill would understand them. And so like I said,
10 somebody that's treating a patient isn't going to be thinking
11 that I can run to the lab, determine these impurities and get
12 waste and go back and deliver that waste to a human.

13 THE COURT: Okay.

14 MS. GAGLIARDI: Thank you.

15 MR. REMUS: Judge, Sandoz's position on this term is
16 very similar to its position on administering terms, and that
17 is the claims mean what they say. And here the disputed
18 claim, claim 11 of '209 and claim 2 of the '785 specifically
19 say the impurities are determined "based on." Not that they
20 can be determined or it's capable of determining, but they are
21 determined. So that language is very clear. And that's
22 solely what Sandoz asked the Court to adopt for its claim
23 construction.

24 If we look at the comparison of claim 1 and claim 2 of
25 the '785 that Ms. Gagliardi also referred to, it drives home

1 how important it is that one actually practiced the claimed
2 HPLC method to infringe. That's because if we look at claim 1
3 of the '785 patent -- this is on slide 44 highlighted in
4 green, it's the same color scheme as the administering
5 terms -- we have the properties of the formulation that's
6 being administered. It spells out exactly what the impurities
7 are.

8 Then in claim 2, highlighted in yellow, we have the
9 HPLC method. If claim 2 simply means that it's capable of
10 determining those impurities, it does not further limit claim
11 1. Claim 2 is now superfluous. If you don't have to practice
12 that method, then claim 2 adds nothing and you're limited to
13 claim 1. And there's a presumption that claim 2 should add a
14 further limitation, that that claim should have meaning. And
15 that's consistent with what we see in the specification.

16 On slide 45 we highlight at least six examples from the
17 '209 patent. I won't go through all six examples. The Court
18 has the benefit of the examples in the slide deck in our
19 brief, but the point is throughout the specification the
20 inventors described the HPLC method as something that is
21 actually performed, not something that simply can be
22 performed.

23 So on that, Your Honor, we think the claim language is
24 clear. We ask the Court to require that to infringe those
25 claims, one has to actually perform the HPLC method. Thank

1 you.

2 MS. GAGLIARDI: I would submit that claim 2 does add
3 something. It addresses the required proof that you need to
4 show that that limitation is met. Here we're talking about a
5 difference between the active infringement and the proof
6 required to establish infringement. Thank you.

7 MR. REMUS: Your Honor, very briefly, I was just
8 reminded I forgot to mention one thing. On Your Honor's
9 question about the nonsensicality argument, we think that's
10 been disclosed at this point in time. Under Sandoz's claim
11 construction the claims are absolutely capable of being
12 infringed. It's not a situation where to test you have to
13 destroy an entire batch. If you want to test it, you take a
14 sample out of a commercial batch, you test that sample. The
15 rest of the batch is perfectly fine. It's not destroyed. So
16 Sandoz's construction is not nonsensical. Thank you.

17 THE COURT: Anything further?

18 So my thought of moving forward is to permit counsel to
19 submit not more than ten pages, a written closing argument.
20 Is that acceptable?

21 MR. REMUS: Yes, Your Honor.

22 MR. BLACK: Yes, Your Honor.

23 THE COURT: How long do you need to do that? There
24 will be simultaneous submissions.

25 MR. BLACK: Ten days, Your Honor.

1 MR. REMUS: Next Friday.

2 THE COURT: Does that work?

3 MR. BLACK: That's fine. Yes.

4 THE COURT: Nobody likes Kansas City or San
5 Francisco. I guess it's before the Super Bowl, so you're
6 okay.

7 MR. REMUS: Well, I have to be careful, though, Your
8 Honor, because Ms. Lydigsen is a huge Kansas City fan. She
9 has her Kansas City ski cap with her, so she will be gearing
10 up for the big game.

11 MR. BLACK: I'm still rooting for the Eagles.

12 THE COURT: Well, you have Randy Reid, I guess.

13 MR. BLACK: We do. Maybe next year.

14 THE COURT: Is next Friday okay, or do you need more
15 time?

16 MR. BLACK: That's fine with us.

17 THE COURT: You okay? Get it off your plate
18 before --

19 MR. REMUS: Before the big game. We can rest on
20 Sunday.

21 THE COURT: Counsel, thank you very much. I will
22 never forget how I spent my Martin Luther King weekend of
23 2020, and I thank you for that. I thank you for resolving at
24 least one of the claims. When you talk to Judge Arpert, and I
25 know you're going to be speaking with him momentarily, perhaps

1 you can come into an agreement on some of the other claims.
2 It seems that you're very close on at least two of the four.
3 So if you can work it out, that would be great. If not,
4 you'll get your decision as quickly as possible.

5 MR. BLACK: Thank you, Your Honor.

6 MR. REMUS: Thank you, Judge.

7 (Court concludes at 10:56 a.m.)
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

	15 [6] - 43:21, 44:10, 46:5, 47:2, 47:20, 48:24 16 [9] - 4:18, 5:1, 6:5, 6:13, 11:14, 12:22, 15:8, 15:17 17 [1] - 15:9 18 [5] - 9:21, 11:1, 14:18, 45:15 19 [1] - 6:5 19104 [1] - 1:21	45 [1] - 58:16 455 [1] - 2:7	acetate [1] - 30:25 acetic [1] - 6:9 acid [3] - 6:9, 20:8, 23:9 act [2] - 55:17, 55:25 ACTION [1] - 1:3 active [3] - 23:3, 54:15, 59:5 add [7] - 39:18, 39:25, 40:3, 40:13, 40:15, 58:13, 59:2 additional [3] - 11:7, 31:20, 42:12 address [1] - 15:10 addressed [1] - 37:19 addresses [2] - 36:17, 59:3 addressing [1] - 4:8 adds [1] - 58:12 administer [7] - 5:22, 6:24, 8:4, 8:20, 9:13, 16:4, 16:11 administered [16] - 5:7, 5:12, 5:18, 5:24, 8:1, 8:13, 9:15, 12:23, 12:25, 13:13, 16:9, 16:22, 35:11, 46:14, 47:8, 58:6 administering [12] - 4:9, 6:15, 8:3, 10:2, 11:4, 11:5, 13:4, 13:5, 16:7, 17:2, 57:16, 58:4 administration [19] - 5:20, 6:8, 6:14, 6:16, 6:21, 7:19, 13:2, 36:10, 38:16, 38:17, 39:8, 44:3, 44:10, 46:6, 46:10, 46:11, 46:16, 47:16 admission [1] - 15:24 adopt [2] - 14:11, 57:22 advanced [1] - 7:14 advancing [1] - 7:12 advantage [2] - 36:18, 38:23 advantages [7] - 36:8, 36:9, 38:1, 38:2, 38:6, 38:10, 52:24 adversely [1] - 40:16 affect [6] - 30:13, 31:3, 31:13, 40:7, 42:19, 43:1 affecting [2] - 40:5, 40:14 affects [4] - 31:21, 37:16, 40:11, 40:16 agree [4] - 23:2, 40:18, 43:4, 45:6	agreed [2] - 4:7, 22:13 agreement [2] - 22:19, 61:1 aid [2] - 13:16, 17:15 aided [1] - 1:25 Alka [1] - 7:5 Alka-Seltzer [1] - 7:5 allows [2] - 30:8, 56:17 almost [3] - 5:23, 12:12, 16:7 alone [1] - 51:17 ambiguity [1] - 45:9 America [2] - 13:19, 13:21 amino [2] - 20:8, 23:9 amorphous [1] - 19:20 amount [3] - 36:2, 50:24, 51:1 amounts [1] - 46:15 analogs [1] - 27:21 analogy [1] - 55:10 analysis [2] - 31:8, 48:19 ANDA [1] - 23:5 animal [3] - 26:22, 26:24, 29:25 animals [2] - 23:13, 23:15 answer [1] - 33:3 antidiuresis [1] - 26:9 apparent [2] - 40:15, 41:6 appear [1] - 12:7 appearances [1] - 3:7 apples [2] - 53:15 applicable [1] - 33:15 application [1] - 8:12 applies [3] - 8:17, 9:8, 50:10 apply [1] - 30:15 aqueous [2] - 26:10, 35:20 Arch [1] - 1:20 area [1] - 24:13 areas [1] - 18:21 Arg [5] - 20:6, 20:8, 20:9, 20:13, 20:20 arginine [32] - 18:6, 18:15, 18:24, 20:4, 20:7, 20:14, 20:17, 20:18, 20:21, 20:23, 21:15, 21:22, 22:17, 22:24, 23:8, 24:25, 25:9, 25:19, 26:7, 26:11, 27:7, 27:9, 27:13, 27:20, 27:23, 27:24, 29:8, 29:13, 29:19			
'102 [1] - 37:9 '103 [1] - 37:9 '209 [5] - 8:7, 54:16, 55:7, 57:18, 58:17 '223 [2] - 9:22, 50:20 '239 [11] - 5:14, 5:15, 10:17, 11:15, 11:18, 11:22, 11:23, 11:25, 12:19, 12:21, 24:5 '478 [4] - 30:17, 30:18, 41:22, 44:21 '526 [9] - 6:4, 11:15, 11:20, 11:23, 11:25, 12:24, 13:1, 13:5, 15:7 '785 [5] - 54:17, 57:18, 57:25, 58:3	2 2 [14] - 6:12, 24:9, 41:23, 54:17, 54:23, 57:18, 57:24, 58:8, 58:9, 58:11, 58:12, 58:13, 59:2 2.1 [4] - 10:10, 14:22, 15:1, 15:12 20 [3] - 13:20, 15:5, 50:4 2015 [1] - 29:25 2020 [3] - 1:11, 3:3, 60:23 21 [7] - 1:11, 2:3, 3:3, 10:9, 14:21, 15:1, 15:12 215 779-6437 [1] - 1:24 24 [2] - 50:25, 51:3 25 [5] - 24:24, 25:12, 28:22, 50:4, 50:25 26 [3] - 24:24, 25:12, 43:22 28 [1] - 46:13 2929 [1] - 1:20	5 5 [1] - 8:7 502 [1] - 1:16 52 [1] - 28:21 55 [1] - 56:25 56 [2] - 36:7, 37:25 57 [1] - 36:15 58 [2] - 28:8 59 [1] - 37:22	6 6 [1] - 7:24 60 [2] - 38:4, 50:25 60611 [1] - 2:8	7 7 [3] - 8:16, 46:9, 46:13 75 [1] - 50:3	8 8 [2] - 6:12, 7:15 8th [1] - 23:14	9 9 [1] - 9:7 99 [1] - 50:8 9:32 [2] - 1:12, 3:3	A a.m [3] - 1:12, 3:3, 61:7 able [4] - 41:14, 41:17, 43:5, 53:7 ABRAHAM [3] - 2:2, 3:12, 3:16 Abraham [1] - 3:13 absolutely [1] - 59:11 acceptability [7] - 36:19, 38:4, 39:1, 39:25, 43:18, 44:11, 47:11 acceptable [8] - 30:24, 38:7, 39:2, 40:2, 40:4, 40:7, 47:14, 59:20 accepted [1] - 18:12 accordance [2] - 29:14, 34:2 according [2] - 16:23, 24:16 accused [1] - 31:11
0	3 3 [4] - 19:16, 20:17, 24:9, 30:2 3.8 [1] - 6:10 35 [1] - 43:10 3600 [1] - 2:7 37 [1] - 24:17 38 [1] - 20:5 39 [1] - 20:13 3:18-cv-14895-BRM-DEA [1] - 1:4	4 4 [3] - 24:9, 44:21, 46:9 400 [2] - 13:23, 13:24 402 [1] - 1:10 43 [1] - 21:1 44 [2] - 21:16, 58:3					
01 [5] - 8:11, 9:11, 14:24, 15:9, 15:21 07 [5] - 8:11, 9:11, 14:25, 15:9, 15:21 08540 [2] - 1:17, 2:4 08608 [1] - 1:11							
1	1 [48] - 5:20, 6:5, 8:6, 10:8, 11:14, 11:15, 11:18, 11:20, 11:22, 12:21, 13:2, 13:4, 15:7, 15:16, 19:7, 19:15, 19:22, 20:11, 20:20, 20:22, 21:1, 23:24, 24:25, 25:3, 25:20, 28:15, 28:18, 30:18, 30:23, 41:22, 42:12, 49:25, 50:4, 50:8, 50:10, 50:12, 50:13, 50:14, 52:9, 57:24, 58:2, 58:11, 58:13 1,000 [4] - 49:11, 49:14, 49:25, 50:12 1.821 [1] - 24:17 10 [4] - 50:13, 55:11, 55:12, 55:19 100 [6] - 49:12, 49:15, 50:2, 50:14 104 [1] - 1:16 10:56 [1] - 61:7 11 [4] - 41:23, 54:16, 55:7, 57:18 112 [1] - 43:10 12 [1] - 6:3 12-hour [1] - 49:17 13 [1] - 51:1						

<p>argue [1] - 4:7 argues [1] - 31:25 argument [13] - 4:20, 5:3, 7:8, 16:24, 22:4, 37:9, 37:20, 38:2, 39:9, 39:12, 39:16, 59:9, 59:19 arguments [4] - 12:13, 21:22, 34:19, 37:4 Arpert [2] - 3:23, 60:24 art [22] - 16:13, 22:16, 22:25, 27:1, 27:18, 27:22, 31:12, 33:22, 34:12, 34:13, 36:6, 39:24, 46:17, 47:3, 47:6, 47:17, 48:13, 49:3, 50:15, 52:3, 52:6, 52:25 article [1] - 27:18 artificial [2] - 21:2, 21:3 assert [1] - 36:12 assertion [2] - 28:14, 29:11 assessment [1] - 43:8 associate [1] - 3:18 attached [1] - 15:7 attempt [2] - 23:22, 27:6 attempting [1] - 25:18 attention [2] - 9:2, 43:15 author [1] - 27:19 AVP [2] - 20:18, 27:20 aware [1] - 3:20</p>	<p>45:5, 45:15, 45:20, 46:19, 47:18, 48:1, 48:10, 48:13, 49:9, 50:18, 51:8, 51:11 basis [2] - 35:2, 39:20 batch [3] - 59:13, 59:14, 59:15 Baxalta [1] - 13:7 beating [1] - 17:11 begin [1] - 25:14 begins [1] - 14:24 behalf [2] - 3:9, 54:8 beings [1] - 16:12 below [4] - 19:11, 19:14, 19:15, 20:11 bench [1] - 32:11 benchmark [1] - 50:16 benchmarks [2] - 49:19, 50:5 benefit [1] - 58:18 best [1] - 32:24 better [1] - 33:9 between [8] - 10:24, 16:17, 18:13, 23:12, 30:8, 30:11, 50:11, 59:5 big [2] - 60:10, 60:19 bit [3] - 23:11, 33:11, 44:8 bits [1] - 53:5 BLACK [17] - 1:19, 3:6, 3:24, 4:5, 4:14, 4:17, 5:15, 7:9, 12:20, 14:14, 59:22, 59:25, 60:3, 60:11, 60:13, 60:16, 61:5 black [3] - 9:18, 9:20, 17:11 Black [2] - 3:10, 4:6 black's [1] - 10:20 blank [1] - 9:5 block [1] - 3:25 blood [5] - 5:10, 6:6, 16:11, 36:23, 36:24 blow [1] - 36:24 Bob [1] - 17:24 body [3] - 21:8, 21:10, 42:2 bottle [4] - 5:18, 8:18, 8:19, 9:10 bottom [2] - 20:12, 43:15 boundaries [3] - 48:12, 49:19, 50:17 boundary [1] - 49:7 Bowl [1] - 60:5 box [3] - 20:6, 20:12, 56:12 brain [2] - 26:1, 26:3 breach [1] - 44:4</p>	<p>bread [2] - 13:22, 13:24 BRIAN [3] - 1:13, 1:19, 3:2 brief [8] - 4:8, 4:22, 15:4, 17:1, 32:14, 34:22, 45:15, 58:19 briefing [1] - 15:10 briefly [3] - 27:5, 51:23, 59:7 briefs [2] - 12:4, 12:14 BRINKS [1] - 2:5 broadly [1] - 24:11 brought [1] - 14:1 Buck [4] - 47:3, 47:5, 47:12, 47:16 buffer [1] - 30:25 Building [1] - 1:10 bunch [1] - 35:25 burden [10] - 33:15, 34:3, 34:4, 34:11, 40:20, 40:21, 44:18, 46:22, 53:19, 55:21 burnt [1] - 13:24 BY [4] - 1:16, 1:19, 2:2, 2:6</p>	<p>certain [1] - 14:21 certainly [3] - 17:9, 44:16, 53:18 certainty [7] - 33:23, 34:14, 34:17, 37:14, 41:16, 43:12, 48:15 CFR [2] - 24:17, 28:7 chance [1] - 15:4 changed [2] - 29:16, 29:24 changing [1] - 13:3 characteristics [10] - 6:2, 30:14, 31:9, 31:17, 31:22, 32:19, 33:4, 36:12, 36:16, 42:20 charcoal [1] - 13:25 Chef [2] - 13:19, 13:21 chemical [3] - 19:16, 20:12, 20:19 chemistry [2] - 56:4, 56:24 Chicago [1] - 2:8 chose [1] - 42:16 chromatography [1] - 56:3 Cira [1] - 1:20 circuit [14] - 10:14, 12:15, 13:8, 25:6, 31:6, 32:14, 34:23, 35:7, 42:22, 45:21, 48:19, 51:16, 54:3 circumstances [1] - 37:18 cite [4] - 29:1, 29:5, 29:14, 34:20 cited [8] - 12:13, 28:21, 29:3, 29:23, 30:9, 32:13, 42:22, 45:15 City [3] - 60:4, 60:8, 60:9 Cityfront [1] - 2:7 CIVIL [1] - 1:3 claim [128] - 4:18, 4:23, 5:1, 5:25, 6:1, 6:4, 6:5, 6:13, 6:18, 7:12, 7:13, 7:19, 8:5, 8:6, 9:4, 9:16, 11:14, 11:15, 11:18, 11:20, 11:21, 12:12, 12:15, 12:16, 12:17, 12:20, 12:21, 13:2, 13:4, 13:21, 14:12, 15:6, 15:7, 15:8, 15:9, 15:16, 15:17, 15:20, 15:23, 16:23, 17:11, 17:13, 17:14, 17:20, 23:20, 24:4, 24:14, 24:15, 24:20, 27:6,</p>	<p>28:13, 30:14, 30:18, 30:23, 31:15, 31:16, 32:1, 32:3, 32:5, 32:6, 32:15, 32:19, 32:22, 33:16, 34:9, 34:16, 34:17, 35:16, 38:13, 41:22, 42:2, 42:11, 42:12, 42:16, 42:18, 42:25, 43:3, 45:10, 46:20, 46:24, 48:21, 49:4, 49:20, 50:7, 51:21, 52:9, 52:24, 53:3, 53:8, 54:13, 54:16, 54:17, 54:18, 54:23, 55:3, 55:4, 55:6, 55:7, 55:10, 55:14, 55:15, 55:19, 57:18, 57:22, 57:24, 58:2, 58:8, 58:9, 58:10, 58:11, 58:12, 58:13, 58:14, 58:23, 59:2, 59:10 claimants [1] - 24:8 claimed [14] - 9:10, 17:6, 19:25, 21:12, 29:16, 29:17, 31:9, 31:22, 35:8, 35:10, 36:5, 36:13, 42:20, 58:1 claiming [4] - 21:11, 21:13, 45:4, 49:18 claims [59] - 4:24, 5:4, 5:8, 5:19, 6:5, 8:3, 8:15, 8:23, 8:25, 9:14, 10:16, 10:17, 12:10, 12:11, 13:6, 13:10, 13:12, 13:17, 14:2, 14:5, 14:8, 14:9, 14:10, 15:7, 16:2, 16:6, 16:15, 17:9, 17:17, 24:6, 24:9, 24:13, 27:24, 28:2, 28:11, 28:15, 30:6, 30:19, 33:21, 34:12, 34:13, 34:25, 35:14, 38:12, 39:5, 40:17, 41:15, 41:23, 47:22, 51:7, 51:18, 54:16, 56:21, 57:17, 58:25, 59:11, 60:24, 61:1 clarity [1] - 41:1 Clarkson [1] - 1:10 clear [35] - 9:19, 12:9, 12:15, 13:9, 13:12, 19:24, 20:22, 20:24, 21:4, 21:15, 21:19, 22:1, 22:7, 25:5, 25:22, 28:19, 29:7, 29:9, 29:10, 30:7,</p>
C				
<p>cannot [4] - 13:15, 13:17, 16:10, 37:13 cap [1] - 60:9 capable [3] - 57:20, 58:9, 59:11 care [1] - 56:23 careful [1] - 60:7 Carnegie [1] - 1:16 carve [1] - 44:1 case [38] - 5:17, 6:22, 10:14, 11:24, 12:14, 13:7, 13:19, 13:21, 13:25, 14:4, 18:10, 21:10, 22:22, 23:25, 25:8, 32:13, 32:14, 32:15, 33:24, 34:2, 34:20, 34:22, 34:23, 35:7, 35:9, 37:7, 37:18, 42:21, 43:2, 45:24, 46:2, 46:4, 51:14, 51:20, 53:22, 53:24, 53:25 cases [4] - 17:12, 17:13, 42:23, 45:14 causes [1] - 26:8 cells [1] - 25:25 celsius [5] - 6:12, 50:3, 50:4, 50:25, 51:3 Center [1] - 1:16 Centre [1] - 1:20</p>				

<p>33:5, 33:25, 34:3, 34:5, 35:4, 38:19, 39:23, 40:22, 48:5, 52:11, 53:10, 53:19, 53:24, 57:21, 58:24</p> <p>clearly [6] - 34:10, 35:10, 38:6, 39:10, 40:14, 45:24</p> <p>CLERK [1] - 4:1</p> <p>client [2] - 3:17, 3:20</p> <p>clinical [2] - 14:7, 47:12</p> <p>close [1] - 61:2</p> <p>closed [1] - 42:17</p> <p>closing [1] - 59:19</p> <p>co [2] - 3:14, 47:8</p> <p>co-administered [1] - 47:8</p> <p>co-counsel [1] - 3:14</p> <p>colleague [1] - 3:10</p> <p>collection [1] - 45:14</p> <p>color [2] - 11:2, 58:4</p> <p>column [13] - 28:22, 43:21, 44:9, 44:15, 44:21, 46:5, 46:9, 46:13, 47:2, 47:20, 48:24, 56:16, 56:17</p> <p>columns [4] - 24:24, 25:1, 25:2, 25:12</p> <p>coming [1] - 34:15</p> <p>Commencing [1] - 1:12</p> <p>comments [2] - 10:20, 17:2</p> <p>commercial [1] - 59:14</p> <p>common [1] - 42:7</p> <p>COMPANY [1] - 1:5</p> <p>compare [1] - 9:24</p> <p>comparing [1] - 53:14</p> <p>comparison [2] - 11:14, 57:24</p> <p>comparisons [1] - 53:15</p> <p>compendium [1] - 26:18</p> <p>completely [9] - 7:20, 9:12, 9:13, 10:12, 11:10, 11:20, 12:2, 13:5, 52:21</p> <p>complicated [1] - 23:9</p> <p>components [6] - 30:22, 42:24, 54:20, 56:5, 56:15, 56:18</p> <p>composition [15] - 5:1, 6:8, 6:11, 11:4, 15:8, 15:9, 15:11, 21:18, 46:14, 54:18, 54:19, 54:20, 54:21, 55:3, 57:1</p>	<p>compositions [4] - 21:13, 33:10, 35:11, 35:23</p> <p>compound [1] - 21:11</p> <p>compounds [1] - 19:6</p> <p>comprised [1] - 36:16</p> <p>comprising [5] - 30:8, 42:10, 42:13, 54:20</p> <p>computer [1] - 1:25</p> <p>computer-aided [1] - 1:25</p> <p>concentration [25] - 6:9, 6:17, 8:10, 8:15, 8:22, 9:10, 9:12, 9:14, 9:15, 10:7, 10:10, 11:8, 11:12, 11:24, 13:4, 13:6, 13:13, 14:15, 14:24, 15:12, 15:16, 15:18, 15:21, 17:3, 18:12</p> <p>concentrations [2] - 11:21, 16:23</p> <p>concerned [1] - 13:21</p> <p>conclude [1] - 39:21</p> <p>concludes [1] - 61:7</p> <p>conclusion [1] - 53:6</p> <p>conclusive [1] - 17:15</p> <p>condition [1] - 35:13</p> <p>conditions [2] - 5:9, 52:9</p> <p>confer [1] - 22:22</p> <p>confirms [1] - 29:11</p> <p>conflate [1] - 10:17</p> <p>confused [2] - 29:11, 52:18</p> <p>confusion [1] - 32:12</p> <p>Connolly [4] - 7:14, 7:18, 9:1, 18:10</p> <p>Connolly's [1] - 4:13</p> <p>consider [2] - 17:16, 31:7</p> <p>considering [1] - 17:7</p> <p>considers [1] - 17:17</p> <p>consistent [4] - 15:3, 21:19, 26:16, 58:15</p> <p>consisting [1] - 42:24</p> <p>consists [10] - 30:4, 30:10, 41:19, 41:25, 42:4, 42:13, 42:17, 43:3, 43:6, 48:9</p> <p>construction [45] - 7:12, 7:13, 7:15, 7:16, 7:20, 7:24, 8:2, 8:17, 8:21, 9:6, 9:7, 9:8, 13:9, 13:17, 14:11, 14:12, 16:17, 16:20, 17:19, 17:20, 18:5, 18:7, 18:8, 22:18, 22:20, 22:24, 24:23, 30:4, 31:15,</p>	<p>32:7, 32:16, 32:22, 33:16, 41:18, 43:4, 43:16, 51:21, 53:9, 54:9, 54:11, 54:12, 57:6, 57:23, 59:11, 59:16</p> <p>constructions [1] - 18:5</p> <p>contain [1] - 54:25</p> <p>container [1] - 56:19</p> <p>contains [2] - 54:22, 54:24</p> <p>contemplates [1] - 28:9</p> <p>contend [1] - 43:17</p> <p>contended [1] - 46:1</p> <p>contends [1] - 54:13</p> <p>context [6] - 5:19, 17:16, 35:9, 43:13, 48:16, 57:8</p> <p>contraction [1] - 26:8</p> <p>contrast [2] - 9:6, 9:24</p> <p>control [1] - 17:14</p> <p>controls [1] - 17:13</p> <p>convincing [4] - 34:3, 35:4, 40:22, 53:10</p> <p>copy [1] - 53:23</p> <p>Coralic [1] - 17:4</p> <p>core [2] - 4:20, 5:17</p> <p>correct [2] - 5:5, 17:19</p> <p>counsel [11] - 3:7, 3:14, 7:10, 28:4, 28:6, 40:18, 45:12, 51:13, 53:20, 59:18, 60:21</p> <p>couple [1] - 24:3</p> <p>course [1] - 46:11</p> <p>Court [19] - 1:23, 3:14, 3:17, 9:5, 14:11, 16:20, 31:7, 32:10, 33:24, 34:2, 39:21, 40:19, 51:9, 53:5, 53:17, 57:22, 58:17, 58:24, 61:7</p> <p>COURT [52] - 1:1, 3:4, 3:7, 3:19, 3:22, 3:25, 4:1, 4:2, 4:12, 4:16, 5:13, 7:8, 7:10, 12:19, 14:13, 14:15, 16:25, 17:22, 18:3, 18:23, 19:1, 22:10, 24:2, 28:3, 30:2, 32:8, 32:13, 33:1, 33:13, 33:19, 40:18, 41:3, 41:5, 41:10, 44:16, 44:25, 45:6, 45:12, 51:22, 53:20, 54:5, 55:8, 57:6, 57:13, 59:17, 59:23, 60:2, 60:4, 60:12,</p>	<p>60:14, 60:17, 60:21</p> <p>court [5] - 3:1, 13:8, 45:19, 48:10, 54:1</p> <p>Courthouse [1] - 1:10</p> <p>courts [3] - 32:19, 35:1</p> <p>cover [6] - 7:19, 16:16, 25:8, 42:11, 50:7, 50:17</p> <p>covered [1] - 50:10</p> <p>covering [1] - 13:2</p> <p>covers [1] - 49:21</p> <p>crisp [1] - 13:25</p> <p>crux [1] - 23:18</p> <p>current [2] - 29:25, 35:23</p> <p>cut [1] - 45:12</p>	<p>D</p> <p>days [1] - 59:25</p> <p>deal [2] - 12:12, 43:3</p> <p>deals [1] - 16:11</p> <p>DECHERT [2] - 1:15, 1:18</p> <p>Dechert [1] - 3:9</p> <p>decide [1] - 39:14</p> <p>deciding [2] - 33:17, 51:25</p> <p>decision [7] - 4:13, 33:11, 42:21, 45:18, 48:8, 51:16, 61:4</p> <p>deck [1] - 58:18</p> <p>declaration [1] - 17:4</p> <p>declarations [2] - 51:15, 54:2</p> <p>decomposition [2] - 49:23, 49:25</p> <p>Defendant [2] - 2:4, 2:8</p> <p>Defendants [1] - 1:9</p> <p>defense [1] - 34:1</p> <p>defenses [1] - 34:1</p> <p>define [2] - 19:5, 25:6</p> <p>defined [2] - 18:23, 25:4</p> <p>defines [2] - 12:22, 12:24</p> <p>defining [1] - 49:7</p> <p>definite [6] - 43:9, 43:11, 48:4, 48:5, 48:14, 49:2</p> <p>definiteness [1] - 48:7</p> <p>definition [3] - 21:23, 22:3, 25:5</p> <p>degradation [2] - 19:14, 35:21</p> <p>degrade [1] - 35:21</p> <p>degrades [2] - 35:20, 56:6</p>	<p>degree [4] - 34:14, 41:16, 50:3, 50:4</p> <p>degrees [7] - 6:12, 13:23, 13:24, 50:3, 50:4, 50:25, 51:2</p> <p>Delaware [10] - 5:3, 7:10, 7:11, 16:17, 18:9, 18:10, 22:11, 22:12, 22:13, 22:18</p> <p>deliver [1] - 57:12</p> <p>deny [1] - 53:25</p> <p>dependent [8] - 6:5, 12:16, 15:7, 24:8, 41:23, 54:23, 55:15, 55:19</p> <p>DEPUTY [1] - 4:1</p> <p>derived [4] - 18:21, 20:25, 21:5</p> <p>describe [5] - 23:11, 26:6, 27:23, 36:8, 46:7</p> <p>described [7] - 18:6, 35:18, 35:25, 38:22, 38:23, 50:6, 58:20</p> <p>describes [9] - 7:7, 12:6, 27:19, 46:5, 49:5, 49:10, 49:23, 50:21, 52:8</p> <p>describing [4] - 10:20, 37:25, 55:4, 57:3</p> <p>description [6] - 10:22, 10:24, 21:3, 28:13, 42:8, 46:2</p> <p>destroy [1] - 59:13</p> <p>destroyed [1] - 59:15</p> <p>detail [3] - 11:3, 11:7</p> <p>details [1] - 19:16</p> <p>determination [1] - 52:2</p> <p>determine [11] - 31:19, 34:25, 41:17, 54:14, 55:2, 55:5, 55:13, 55:16, 56:9, 57:4, 57:11</p> <p>determined [4] - 54:10, 57:19, 57:20, 57:21</p> <p>determining [4] - 51:18, 56:25, 57:20, 58:10</p> <p>dextrose [1] - 8:19</p> <p>difference [6] - 11:8, 16:16, 18:13, 18:14, 23:12, 59:5</p> <p>different [22] - 7:13, 9:12, 9:16, 10:10, 10:13, 10:18, 11:11, 11:12, 11:20, 11:21, 11:24, 12:2, 13:5, 23:6, 32:6, 42:6,</p>
---	---	--	--	--	---

46:7, 50:11, 51:10, 51:11, 52:8, 56:18 differentiates [1] - 36:5 differentiation [6] - 12:13, 12:16, 17:12, 17:13, 17:14, 17:21 diluent [4] - 5:2, 6:14, 10:7, 15:8 dilute [7] - 7:2, 7:3, 8:19, 8:24, 9:11, 15:17, 15:18 diluted [14] - 5:2, 5:24, 6:14, 10:5, 10:19, 11:5, 11:17, 13:2, 14:20, 14:25, 15:8, 15:11, 15:14, 16:5 diluting [3] - 10:6, 14:20, 39:7 dilution [24] - 4:23, 4:24, 4:25, 5:4, 5:16, 6:24, 7:19, 7:20, 7:21, 8:16, 8:17, 9:3, 9:23, 9:24, 10:3, 10:25, 11:1, 11:6, 11:9, 14:23, 15:2, 16:1, 16:16 direct [1] - 43:14 directed [2] - 13:21, 35:10 directly [1] - 6:22 disagree [1] - 12:4 disclose [1] - 40:25 disclosed [1] - 59:10 discloses [2] - 17:4, 22:16 discretion [2] - 32:20, 32:23 discussed [2] - 6:23, 56:6 discusses [4] - 6:1, 6:19, 6:22, 47:5 discussion [2] - 38:24, 39:6 diseases [2] - 46:8, 46:9 dispositive [1] - 17:8 dispute [8] - 7:23, 21:7, 22:12, 23:18, 23:25, 52:1, 53:13, 54:10 disputed [3] - 18:10, 54:24, 57:17 disputing [1] - 32:16 dissolve [1] - 7:6 distinguish [2] - 22:25, 27:21 DISTRICT [3] - 1:1, 1:1, 1:13 District [1] - 3:2	district [2] - 32:19, 54:1 docket [1] - 32:20 doctor [1] - 5:10 doctors [1] - 7:7 dog [2] - 12:17, 12:19 Donatiello [1] - 3:21 done [7] - 5:2, 7:1, 32:8, 45:16, 45:17, 47:16, 53:2 dosage [12] - 10:4, 10:5, 10:7, 10:11, 10:18, 10:19, 11:5, 14:20, 14:24, 30:22, 42:4, 42:14 dough [1] - 13:22 down [1] - 15:1 Dr [1] - 17:4 drafted [1] - 24:13 drafters [1] - 49:24 draw [1] - 24:25 draws [1] - 56:15 drink [1] - 7:6 drip [1] - 4:25 Drive [1] - 2:7 drives [1] - 57:25 dropped [1] - 29:18 drug [2] - 5:17, 5:23 drugs [1] - 47:8 drum [1] - 17:12 drying [3] - 51:8, 51:10 during [1] - 36:2 Dyk [1] - 13:7	eighth [1] - 23:9 either [3] - 7:2, 11:3, 31:11 element [2] - 14:20, 31:21 elements [6] - 8:25, 42:3, 42:5, 42:11, 42:12, 42:14 elsewhere [1] - 38:20 embodiment [18] - 9:22, 9:23, 10:3, 10:24, 11:3, 11:6, 11:9, 11:10, 11:11, 11:21, 12:5, 14:19, 14:23, 15:25, 16:16, 25:15, 25:21 Embodiments [1] - 38:5 embodiments [15] - 9:21, 10:13, 10:15, 10:16, 10:25, 12:2, 12:6, 12:10, 14:16, 25:16, 28:21, 28:23, 28:25 emergent [1] - 5:10 employ [1] - 40:19 encompassed [2] - 25:23, 27:15 end [3] - 17:14, 19:3, 29:2 ENDO [1] - 1:4 entire [2] - 41:24, 59:13 entirely [1] - 34:19 equally [1] - 12:9 Eric [1] - 3:13 ERIC [1] - 2:2 ESQUIRE [8] - 1:16, 1:19, 1:19, 1:20, 2:2, 2:3, 2:6, 2:6 essentially [10] - 30:4, 37:4, 41:19, 42:5, 42:13, 42:17, 42:24, 43:3, 43:7, 48:9 establish [2] - 35:4, 59:6 evaluation [1] - 48:9 evidence [33] - 5:23, 6:25, 17:7, 17:8, 17:16, 17:18, 26:16, 27:10, 33:6, 33:18, 34:4, 34:15, 34:18, 34:24, 35:4, 35:5, 37:5, 38:19, 39:10, 39:12, 39:20, 40:22, 45:8, 52:3, 52:4, 52:5, 53:9, 53:11, 53:17, 53:22, 55:20, 55:22 ex [1] - 52:19	exact [2] - 11:2, 11:7 exactly [6] - 6:19, 12:17, 14:4, 17:4, 19:6, 58:6 example [11] - 6:24, 8:6, 8:18, 10:14, 11:1, 11:10, 11:19, 15:2, 15:13, 20:9, 46:15 examples [4] - 25:16, 58:16, 58:17, 58:18 exceed [1] - 51:3 exceeded [1] - 51:1 except [1] - 7:17 excerpt [2] - 26:17, 50:20 excerpts [1] - 52:15 exclude [4] - 7:21, 8:21, 9:2, 22:24 exclusively [2] - 12:12, 26:13 exemplary [2] - 9:21, 24:5 existed [1] - 35:18 existence [1] - 20:7 existing [1] - 35:18 exists [1] - 40:22 experiments [1] - 35:25 expert [36] - 13:15, 13:16, 14:1, 14:2, 14:6, 14:8, 32:10, 33:9, 34:15, 34:18, 34:21, 34:24, 35:2, 37:11, 39:13, 39:19, 40:24, 41:8, 41:11, 45:8, 45:23, 51:13, 51:14, 52:1, 52:12, 52:13, 52:16, 52:20, 53:1, 53:4, 53:15, 53:16, 53:22, 54:2 experts [3] - 34:24, 40:7, 40:10 explain [1] - 7:21 explained [2] - 10:14, 52:23 explaining [1] - 21:9 explicitly [3] - 6:21, 22:20, 34:23 expressed [1] - 21:23 expressly [8] - 7:18, 8:15, 9:24, 27:12, 35:14, 36:7, 38:18, 53:22 extensive [2] - 38:24, 39:6 extent [2] - 45:8 extrapolate [1] - 47:20 extrinsic [2] - 26:16, 27:10	F face [5] - 5:4, 12:20, 13:10, 13:12, 14:10 fact [12] - 16:9, 28:14, 29:7, 31:19, 34:6, 34:7, 45:9, 47:2, 47:5, 47:22, 54:1, 54:21 fact-finder [1] - 31:19 failed [3] - 33:22, 34:10, 35:3 fails [1] - 40:25 fall [1] - 42:22 families [1] - 10:13 fan [1] - 60:8 far [2] - 18:14, 25:13 favor [1] - 4:15 FDA [1] - 40:1 featured [1] - 43:22 features [1] - 25:19 federal [15] - 10:14, 12:15, 13:8, 25:6, 31:6, 32:14, 34:23, 35:7, 42:22, 45:20, 45:21, 48:18, 51:16, 54:2 field [3] - 26:19, 27:2 fighting [1] - 22:14 figure [1] - 40:10 file [1] - 15:5 filed [1] - 15:4 final [1] - 39:16 finally [3] - 27:18, 29:5, 47:15 finder [1] - 31:19 fine [4] - 8:21, 59:15, 60:3, 60:16 firm [1] - 3:18 first [27] - 4:9, 5:25, 6:1, 6:7, 17:2, 18:14, 19:7, 23:19, 24:21, 28:7, 31:8, 31:10, 31:14, 32:4, 32:18, 33:3, 33:20, 35:6, 35:16, 37:20, 39:9, 43:25, 49:12, 49:17, 50:1, 56:12 Fisher [1] - 1:10 fit [1] - 4:4 fits [1] - 6:18 five [6] - 43:15, 45:25, 49:11, 49:15, 50:1, 51:2 flag [1] - 46:23 focus [1] - 48:23 focused [1] - 9:2 folks [2] - 16:19, 26:19 follow [3] - 4:12, 7:10, 7:11
--	---	--	--	--

<p>following ^[1] - 25:15 follows ^[1] - 48:10 FOR ^[1] - 1:1 forget ^[1] - 60:22 forgot ^[1] - 59:8 form ^[19] - 5:24, 10:4, 10:5, 10:7, 10:11, 10:18, 10:19, 11:5, 14:20, 14:24, 19:21, 29:9, 30:22, 34:21, 38:16, 39:7, 42:4, 42:14 formally ^[1] - 47:9 forms ^[1] - 23:7 formula ^[1] - 19:17 formulas ^[1] - 21:25 formulate ^[1] - 21:18 formulated ^[5] - 26:10, 26:12, 26:13, 27:8 formulating ^[1] - 35:22 formulation ^[17] - 8:4, 8:9, 8:13, 9:4, 10:1, 11:9, 12:23, 12:25, 22:16, 31:12, 36:10, 44:7, 49:15, 50:1, 50:22, 56:5, 58:5 formulations ^[5] - 35:19, 35:24, 38:5, 47:6, 53:14 forth ^[4] - 4:11, 36:3, 36:11, 36:15 forward ^[2] - 55:21, 59:18 four ^[17] - 4:7, 5:8, 6:12, 15:16, 19:3, 36:15, 37:3, 37:23, 38:18, 38:20, 39:22, 41:21, 43:24, 47:4, 47:20, 48:18, 61:2 fourth ^[2] - 6:15, 44:6 framing ^[1] - 7:22 Francisco ^[1] - 60:5 frequently ^[2] - 8:10, 24:8 Friday ^[2] - 60:1, 60:14 full ^[2] - 16:1, 32:10</p>	<p>gel ^[1] - 40:13 general ^[3] - 11:10, 23:2, 33:24 generally ^[2] - 5:6, 43:4 generic ^[1] - 23:5 generically ^[1] - 24:7 GILSON ^[1] - 2:5 given ^[2] - 6:24, 41:19 GOLDBERG ^[1] - 1:19 govern ^[2] - 13:9, 24:12 governs ^[1] - 18:9 graphic ^[1] - 9:7 great ^[2] - 12:12, 61:3 green ^[8] - 8:7, 9:25, 10:4, 10:6, 11:17, 58:4 guess ^[3] - 5:1, 60:5, 60:12 guidance ^[1] - 43:2 Guy ^[1] - 3:20</p>	<p>hinged ^[1] - 51:13 history ^[7] - 17:18, 33:5, 36:3, 38:25, 48:12, 52:21, 53:2 hit ^[1] - 51:24 hold ^[3] - 4:19, 7:18, 32:21 holds ^[1] - 10:3 home ^[1] - 57:25 honest ^[1] - 16:19 Honor ^[41] - 3:6, 3:8, 3:12, 3:20, 4:5, 4:14, 5:15, 7:15, 12:2, 12:14, 12:21, 13:14, 14:17, 15:6, 17:6, 17:7, 17:17, 17:24, 22:9, 28:5, 30:3, 32:17, 42:22, 45:1, 45:7, 51:23, 51:24, 52:17, 52:20, 53:17, 53:24, 54:3, 54:7, 58:23, 59:7, 59:21, 59:22, 59:25, 60:8, 61:5 Honor's ^[4] - 32:23, 42:9, 43:14, 59:8 HONORABLE ^[1] - 1:13 Honorable ^[1] - 3:1 hormone ^[1] - 26:8 hospital ^[2] - 36:23, 56:22 hour ^[2] - 49:16, 49:17 hours ^[1] - 3:25 HPLC ^[8] - 54:10, 56:1, 56:3, 56:24, 58:2, 58:9, 58:20, 58:25 huge ^[1] - 60:8 human ^[7] - 5:22, 11:4, 11:5, 16:12, 21:8, 40:1, 57:12 humans ^[1] - 18:16 humidity ^[1] - 50:25 hundreds ^[1] - 12:8 hypotension ^[19] - 35:12, 36:21, 36:22, 38:10, 38:12, 38:14, 39:4, 40:9, 43:19, 44:11, 44:15, 44:23, 45:10, 46:8, 47:12, 47:13, 52:7, 52:13, 56:20 hypotensive ^[1] - 52:11 hypothalamus ^[1] - 26:1 HZNP ^[11] - 42:21, 45:17, 45:19, 48:8, 48:17, 48:18, 51:7,</p>	<p>51:13, 53:21, 53:22, 53:25</p>	<p>56:25, 57:1, 57:4, 57:11, 57:19, 58:6, 58:10 INC ^[2] - 1:3, 1:8 include ^[7] - 9:3, 18:16, 21:1, 24:15, 31:2, 42:14, 49:25 included ^[2] - 29:2, 29:15 includes ^[3] - 26:22, 38:24, 40:1 including ^[3] - 14:23, 27:3, 28:17 inclusion ^[1] - 42:24 increasing ^[1] - 6:6 increment ^[1] - 50:8 increments ^[10] - 49:11, 49:12, 49:16, 49:17, 49:18, 50:1, 50:3, 50:4, 50:11, 50:14 indefinite ^[17] - 31:25, 32:1, 32:3, 32:6, 34:7, 34:9, 39:17, 39:22, 40:17, 41:22, 41:23, 48:21, 48:22, 51:12, 51:18, 53:18 indefiniteness ^[6] - 32:5, 33:21, 33:25, 34:3, 34:5, 34:21 independent ^[3] - 12:17, 13:10, 54:18 indicates ^[1] - 49:1 indicating ^[4] - 6:25, 20:6, 20:13, 20:21 indication ^[1] - 51:5 inform ^[4] - 33:22, 34:12, 43:11, 48:14 information ^[2] - 4:9, 21:2 informed ^[1] - 33:11 infringe ^[5] - 11:23, 11:25, 58:2, 58:24 infringed ^[1] - 59:12 infringement ^[7] - 31:7, 31:19, 37:17, 54:15, 55:2, 59:5, 59:6 infringes ^[1] - 55:14 infringing ^[2] - 11:23, 55:17 ingredient ^[2] - 23:4, 31:11 ingredients ^[4] - 30:11, 30:12, 31:2, 40:2 inject ^[2] - 6:22, 40:1 injected ^[2] - 5:11, 40:14 injection ^[11] - 26:21,</p>
<p>G</p>	<p>H</p>	<p>I</p>		
<p>Gagliardi ^[3] - 3:11, 54:8, 57:25 GAGLIARDI ^[6] - 1:20, 54:7, 55:9, 57:7, 57:14, 59:2 game ^[2] - 60:10, 60:19 gearing ^[1] - 60:9</p>	<p>Haemonetics ^[1] - 10:14 half ^[4] - 49:6, 49:10, 49:14, 49:16 happy ^[1] - 32:17 head ^[1] - 51:24 heading ^[2] - 27:14, 46:2 headings ^[1] - 45:25 heard ^[1] - 11:1 hearing ^[2] - 4:3, 32:21 HEARING ^[1] - 1:5 heavily ^[2] - 12:3, 43:23 heavy ^[1] - 34:4 held ^[1] - 3:1 help ^[1] - 49:8 helpful ^[2] - 16:24, 43:2 helps ^[2] - 7:25, 46:23 high ^[1] - 56:3 high-performance ^[1] - 56:3 higher ^[2] - 17:2, 45:3 highlight ^[1] - 58:16 highlighted ^[8] - 8:7, 9:25, 11:2, 11:16, 11:17, 26:23, 58:3, 58:8 highlighting ^[2] - 10:6, 11:16 highlights ^[1] - 52:19 Hill ^[2] - 3:13, 3:18 HILL ^[1] - 2:2</p>	<p>hundreds ^[1] - 12:8 hypotension ^[19] - 35:12, 36:21, 36:22, 38:10, 38:12, 38:14, 39:4, 40:9, 43:19, 44:11, 44:15, 44:23, 45:10, 46:8, 47:12, 47:13, 52:7, 52:13, 56:20 hypotensive ^[1] - 52:11 hypothalamus ^[1] - 26:1 HZNP ^[11] - 42:21, 45:17, 45:19, 48:8, 48:17, 48:18, 51:7,</p>	<p>ID ^[33] - 18:6, 18:23, 19:7, 19:9, 19:11, 19:15, 19:18, 19:21, 20:11, 20:20, 20:25, 22:7, 23:23, 24:6, 24:9, 24:10, 24:14, 24:16, 24:19, 24:25, 25:2, 25:10, 25:20, 28:10, 28:12, 28:15, 28:17, 28:18, 28:24, 29:1, 29:22, 50:9 idea ^[1] - 32:2 identical ^[2] - 7:16, 10:24 identification ^[3] - 28:9, 41:13, 45:16 identified ^[11] - 30:4, 36:18, 37:2, 37:23, 39:11, 43:8, 43:24, 45:21, 48:25, 51:8 identifier ^[1] - 28:12 identifies ^[1] - 47:4 identify ^[10] - 20:3, 37:5, 38:9, 41:1, 43:5, 45:19, 47:1, 48:1, 56:5, 56:18 identifying ^[1] - 28:18 ignore ^[3] - 44:6, 47:22, 52:21 ignoring ^[2] - 9:14, 9:17 IL ^[1] - 2:8 illustrated ^[2] - 19:11, 20:11 illustrative ^[1] - 25:16 images ^[1] - 7:25 impact ^[2] - 30:19, 36:1 implicated ^[1] - 54:16 importance ^[1] - 52:19 important ^[8] - 7:3, 7:17, 7:22, 16:14, 17:10, 23:17, 33:14, 58:1 importantly ^[2] - 7:21, 22:6 imprecision ^[2] - 34:6, 34:8 improper ^[4] - 23:25, 24:2, 24:20, 53:8 impurities ^[19] - 19:18, 50:24, 51:2, 54:9, 54:15, 54:22, 54:24, 55:1, 55:5, 56:7, 56:8, 56:10,</p>	

<p>26:22, 27:12, 27:14, 37:1, 38:15, 39:6, 39:7, 40:12, 43:20, 44:12</p> <p>injections [1] - 38:18</p> <p>INNOVATION [1] - 1:4</p> <p>inquiry [2] - 29:17, 43:5</p> <p>instance [2] - 12:18, 35:14</p> <p>instead [6] - 10:23, 20:9, 20:20, 23:10, 24:11, 49:18</p> <p>intended [2] - 15:25, 24:9</p> <p>intention [1] - 56:8</p> <p>intermuscular [1] - 46:16</p> <p>interpret [2] - 41:10, 53:5</p> <p>intravenous [11] - 6:8, 37:1, 38:15, 38:17, 39:6, 39:7, 40:12, 43:19, 44:12, 46:15, 47:16</p> <p>intravenously [2] - 6:15, 35:11</p> <p>intrinsic [8] - 33:6, 33:18, 37:5, 38:19, 39:10, 52:2, 52:4, 52:5</p> <p>introduce [2] - 3:14, 3:17</p> <p>invalid [2] - 37:9, 51:18</p> <p>invalidate [3] - 32:1, 32:5, 51:7</p> <p>invalidated [1] - 34:20</p> <p>invalidity [7] - 34:1, 35:2, 35:5, 37:8, 37:17, 51:20</p> <p>invent [1] - 35:17</p> <p>invention [19] - 17:6, 20:1, 21:12, 25:17, 29:16, 29:17, 31:4, 31:23, 33:23, 35:8, 35:10, 36:13, 42:20, 43:1, 43:13, 48:16, 49:10, 49:21</p> <p>inventions [4] - 31:9, 36:25, 49:25, 50:7</p> <p>inventors [2] - 52:22, 58:20</p> <p>involve [1] - 16:15</p> <p>involved [3] - 34:6, 34:8, 48:8</p> <p>issue [8] - 9:3, 24:21, 31:12, 31:24, 32:4, 33:10, 39:20, 47:6</p> <p>itself [5] - 24:4, 25:13,</p>	<p>40:23, 45:10, 48:5</p> <p>IV [9] - 4:25, 5:11, 6:25, 10:21, 10:22, 15:23, 16:10, 46:11</p> <p>J</p> <p>January [2] - 1:11, 3:2</p> <p>JERSEY [1] - 1:1</p> <p>Jersey [2] - 1:11, 3:13</p> <p>judge [2] - 52:4, 57:15</p> <p>Judge [13] - 3:2, 3:15, 3:22, 4:12, 7:14, 7:18, 9:1, 13:7, 14:14, 17:1, 18:10, 60:24, 61:6</p> <p>JUDGE [1] - 1:13</p> <p>judges [1] - 45:23</p> <p>jump [2] - 4:9, 4:18</p> <p>juncture [1] - 40:19</p> <p>jury [1] - 32:11</p> <p>K</p> <p>Kansas [3] - 60:4, 60:8, 60:9</p> <p>keep [2] - 15:21, 17:11</p> <p>key [1] - 26:11</p> <p>kilograms [3] - 55:11, 55:12, 55:19</p> <p>kind [5] - 16:22, 30:6, 30:16, 53:17, 55:20</p> <p>kinds [1] - 35:23</p> <p>King [1] - 60:22</p> <p>knock [1] - 41:24</p> <p>knowing [1] - 22:19</p> <p>knowledge [1] - 27:2</p> <p>known [3] - 6:23, 19:11, 40:16</p> <p>knows [2] - 14:2, 14:6</p> <p>L</p> <p>lab [3] - 56:4, 56:24, 57:11</p> <p>label [1] - 29:10</p> <p>labeling [2] - 29:6</p> <p>laid [1] - 43:17</p> <p>Lamb [1] - 13:19</p> <p>Lamb-Weston [1] - 13:19</p> <p>language [4] - 24:15, 25:14, 57:21, 58:23</p> <p>laser [1] - 56:11</p> <p>last [6] - 13:14, 16:25, 42:22, 52:10, 54:6, 54:9</p> <p>LAURA [1] - 2:6</p> <p>Laura [1] - 3:16</p> <p>law [6] - 12:14, 25:6,</p>	<p>34:4, 35:3, 42:21</p> <p>lawyer [2] - 34:19, 52:4</p> <p>lead [1] - 15:23</p> <p>least [6] - 16:18, 37:18, 54:6, 58:16, 60:24, 61:2</p> <p>left [2] - 8:19, 9:9</p> <p>level [11] - 11:2, 11:7, 41:16, 45:3, 49:8, 49:20, 49:21, 49:23, 50:6, 50:9, 50:17</p> <p>lexicography [2] - 25:5, 28:1</p> <p>life [1] - 49:7</p> <p>light [6] - 10:4, 10:6, 11:17, 22:15, 48:11, 52:17</p> <p>likely [1] - 55:22</p> <p>limit [6] - 22:21, 24:9, 25:17, 25:18, 28:1, 58:10</p> <p>limitation [6] - 23:19, 27:5, 54:13, 54:24, 58:14, 59:4</p> <p>limitations [2] - 23:16, 25:12</p> <p>limited [9] - 5:15, 5:16, 13:11, 23:23, 24:22, 26:17, 27:7, 30:18, 58:12</p> <p>limiting [2] - 25:14, 56:8</p> <p>limits [1] - 42:18</p> <p>line [4] - 43:22, 46:9, 46:13, 52:10</p> <p>lined [1] - 18:1</p> <p>lines [1] - 43:15</p> <p>LIONE [1] - 2:5</p> <p>liquid [1] - 56:3</p> <p>list [4] - 24:6, 36:13, 40:1, 46:9</p> <p>listed [6] - 19:14, 20:1, 42:7, 42:25, 44:6, 47:20</p> <p>listing [11] - 19:23, 20:5, 20:6, 20:24, 21:2, 21:14, 21:15, 22:7, 25:3, 28:17, 47:18</p> <p>listings [5] - 19:4, 28:24, 29:1, 29:3, 29:4</p> <p>lists [4] - 27:12, 42:2, 43:22, 44:5</p> <p>literally [1] - 12:7</p> <p>literature [1] - 23:6</p> <p>Lithuanian [1] - 22:16</p> <p>lives [3] - 49:11, 49:14, 49:16</p>	<p>LLC [2] - 1:4, 1:5</p> <p>LLP [4] - 1:15, 1:18, 2:2, 3:9</p> <p>long-term [1] - 35:24</p> <p>look [15] - 4:18, 5:6, 10:5, 10:13, 11:13, 12:15, 14:18, 15:5, 18:4, 24:4, 27:10, 35:6, 51:15, 57:24, 58:2</p> <p>looked [5] - 20:16, 42:12, 45:22, 45:23, 54:1</p> <p>looking [1] - 43:14</p> <p>loss [1] - 38:2</p> <p>low [1] - 36:22</p> <p>lump [1] - 13:25</p> <p>Luther [1] - 60:22</p> <p>Lydigsen [2] - 3:16, 60:8</p> <p>LYDIGSEN [13] - 2:6, 22:9, 22:12, 24:3, 29:20, 40:21, 41:4, 41:6, 41:13, 44:20, 45:1, 45:14, 53:25</p> <p>Lys [3] - 20:9, 20:15, 20:20</p> <p>lysine [10] - 18:16, 18:17, 20:8, 20:14, 23:14, 25:9, 27:13, 27:15, 29:15, 29:18</p> <p>M</p> <p>magic [1] - 24:15</p> <p>majority [1] - 16:5</p> <p>manage [1] - 32:20</p> <p>Mark [1] - 3:14</p> <p>MARK [1] - 2:6</p> <p>MARKMAN [1] - 1:5</p> <p>Markman [2] - 32:21, 51:15</p> <p>MARTIN [1] - 1:19</p> <p>Martin [3] - 3:10, 4:6, 60:22</p> <p>MARTINOTTI [2] - 1:13, 3:2</p> <p>mass [8] - 55:11, 55:12, 55:13, 55:14, 55:16, 55:19, 55:22</p> <p>material [2] - 23:24, 39:19</p> <p>materially [11] - 7:13, 30:13, 31:3, 31:13, 31:21, 37:16, 40:5, 40:10, 40:14, 42:19, 42:25</p> <p>materials [1] - 42:18</p> <p>matter [3] - 8:8, 18:22, 35:3</p>	<p>McKay [1] - 1:23</p> <p>McKay-Soule [1] - 1:23</p> <p>mean [6] - 21:24, 34:6, 34:8, 44:16, 44:24, 57:17</p> <p>meaning [18] - 9:17, 12:21, 13:3, 13:16, 14:5, 14:9, 17:9, 17:17, 23:3, 25:7, 28:2, 30:7, 30:15, 30:22, 31:24, 41:20, 54:12, 58:14</p> <p>means [6] - 10:18, 25:3, 38:3, 39:25, 46:24, 58:9</p> <p>meant [1] - 52:18</p> <p>measure [1] - 15:22</p> <p>measured [1] - 49:15</p> <p>measurements [1] - 50:13</p> <p>measures [1] - 49:5</p> <p>mechanical [1] - 1:25</p> <p>medical [1] - 26:19</p> <p>medicine [1] - 7:3</p> <p>meet [4] - 8:25, 22:22, 34:10, 55:21</p> <p>meeting [1] - 53:10</p> <p>Megan [1] - 1:23</p> <p>megansoule430@gmail.com [1] - 1:23</p> <p>mention [3] - 4:24, 9:23, 59:8</p> <p>mentioned [4] - 5:14, 9:18, 38:12, 42:6</p> <p>mentions [3] - 9:24, 38:3, 54:1</p> <p>merits [1] - 18:11</p> <p>met [3] - 15:21, 53:19, 59:4</p> <p>method [18] - 6:6, 6:20, 13:22, 42:3, 54:10, 55:3, 55:6, 55:24, 56:19, 56:23, 58:2, 58:9, 58:12, 58:20, 58:25</p> <p>microgram [2] - 15:1, 15:2</p> <p>micrograms [6] - 10:9, 10:10, 14:21, 14:22, 15:12</p> <p>Microsoft [1] - 34:2</p> <p>might [2] - 28:1, 33:10</p> <p>milligrams [4] - 8:11, 9:11, 10:9, 14:25</p> <p>milliliter [6] - 8:11, 9:11, 10:8, 14:22, 14:25</p> <p>mine [1] - 3:10</p> <p>minute [5] - 5:21,</p>
---	--	--	---	---

<p>16:8, 30:25, 37:7, 45:18</p> <p>minutes ^[1] - 56:25</p> <p>missing ^[1] - 25:2</p> <p>mix ^[1] - 50:12</p> <p>mixing ^[1] - 56:14</p> <p>mobile ^[2] - 56:13, 56:14</p> <p>modulation ^[1] - 44:7</p> <p>molecules ^[1] - 23:10</p> <p>moment ^[1] - 33:7</p> <p>momentarily ^[1] - 60:25</p> <p>months ^[2] - 51:1, 51:3</p> <p>morning ^[11] - 3:4, 3:6, 3:8, 3:10, 3:12, 3:15, 3:21, 17:24, 22:9, 22:10, 54:7</p> <p>most ^[4] - 16:14, 17:9, 22:6, 23:17</p> <p>mouthpiece ^[1] - 41:8</p> <p>moving ^[1] - 59:18</p> <p>MPEP ^[2] - 42:8, 42:21</p> <p>MR ^[45] - 3:6, 3:8, 3:12, 3:15, 3:16, 3:20, 3:24, 4:5, 4:14, 4:17, 5:15, 7:9, 7:11, 12:20, 14:14, 14:17, 17:1, 17:24, 18:4, 18:24, 19:2, 28:5, 30:3, 32:9, 32:15, 33:2, 33:14, 33:20, 45:7, 51:23, 53:21, 57:15, 59:7, 59:21, 59:22, 59:25, 60:1, 60:3, 60:7, 60:11, 60:13, 60:16, 60:19, 61:5, 61:6</p> <p>MS ^[17] - 22:9, 22:12, 24:3, 29:20, 40:21, 41:4, 41:6, 41:13, 44:20, 45:1, 45:14, 53:25, 54:7, 55:9, 57:7, 57:14, 59:2</p> <p>multiple ^[1] - 51:19</p> <p>muscles ^[1] - 26:9</p> <p>must ^[5] - 13:13, 28:11, 43:11, 48:12, 48:14</p>	<p>25:7</p> <p>natural ^[3] - 21:6, 25:8, 29:6</p> <p>naturally ^[7] - 18:20, 21:7, 22:17, 23:15, 26:3, 26:15, 26:25</p> <p>nature ^[2] - 56:1, 57:4</p> <p>Nautilus ^[1] - 33:24</p> <p>necessarily ^[3] - 26:5, 27:3, 27:9</p> <p>need ^[17] - 8:22, 24:15, 24:18, 33:1, 33:7, 40:24, 41:8, 41:11, 44:17, 46:11, 46:17, 50:14, 53:1, 55:20, 59:3, 59:23, 60:14</p> <p>needed ^[3] - 5:9, 25:5, 33:4</p> <p>needing ^[1] - 56:22</p> <p>needs ^[7] - 5:10, 17:6, 26:4, 36:24, 40:19, 45:9, 53:17</p> <p>neurosecretory ^[1] - 25:25</p> <p>never ^[2] - 9:1, 60:22</p> <p>new ^[1] - 47:24</p> <p>NEW ^[1] - 1:1</p> <p>New ^[2] - 1:11, 3:13</p> <p>next ^[8] - 9:19, 17:23, 18:1, 30:3, 38:9, 60:1, 60:13, 60:14</p> <p>NJ ^[2] - 1:17, 2:4</p> <p>nobody ^[1] - 60:4</p> <p>nobody's ^[1] - 29:11</p> <p>non ^[1] - 25:16</p> <p>non-embodiments ^[1] - 25:16</p> <p>none ^[1] - 47:23</p> <p>nonlimiting ^[2] - 25:21, 28:22</p> <p>nonsensical ^[3] - 57:6, 57:7, 59:16</p> <p>nonsensicality ^[1] - 59:9</p> <p>normal ^[2] - 32:6, 33:16</p> <p>North ^[1] - 2:7</p> <p>note ^[1] - 14:24</p> <p>noted ^[1] - 38:22</p> <p>notes ^[1] - 21:10</p> <p>nothing ^[8] - 4:24, 6:21, 12:5, 27:25, 29:4, 29:24, 54:3, 58:12</p> <p>notion ^[2] - 12:4, 53:12</p> <p>notwithstanding ^[1] - 14:5</p> <p>novel ^[42] - 30:13,</p>	<p>31:3, 31:8, 31:14, 31:17, 31:22, 32:18, 33:3, 35:8, 36:6, 36:12, 36:16, 37:8, 37:10, 37:11, 37:12, 39:13, 39:14, 39:15, 40:25, 41:14, 42:20, 43:1, 43:6, 43:11, 43:17, 45:5, 45:16, 45:20, 46:19, 47:2, 47:19, 47:24, 48:1, 48:11, 48:13, 49:9, 49:10, 49:20, 50:18, 51:9, 51:12</p> <p>novels ^[1] - 40:5</p> <p>novelty ^[1] - 39:12</p> <p>nowhere ^[1] - 5:14</p> <p>NUMBER ^[1] - 1:3</p> <p>number ^[34] - 4:22, 6:3, 6:9, 14:21, 18:7, 19:7, 19:9, 19:10, 19:12, 19:15, 19:19, 19:22, 20:11, 20:20, 21:1, 23:24, 24:14, 24:19, 24:25, 25:3, 25:20, 28:10, 28:13, 28:15, 28:17, 28:18, 29:22, 30:2, 43:5, 47:12, 50:10, 54:25, 56:8, 56:13</p> <p>numbers ^[2] - 24:9, 28:24</p> <p>numerous ^[1] - 49:5</p>	<p>15:25, 16:17, 17:4, 17:8, 17:15, 17:19, 18:8, 18:9, 19:7, 19:12, 19:14, 19:19, 23:18, 26:7, 28:7, 30:5, 30:17, 30:19, 31:18, 37:16, 37:23, 38:1, 38:10, 43:5, 44:1, 45:25, 46:4, 47:3, 48:19, 48:21, 49:6, 49:11, 49:14, 49:16, 50:3, 51:19, 56:13, 58:1, 58:25, 59:8, 60:24</p> <p>ones ^[2] - 30:12, 42:8</p> <p>open ^[2] - 3:1, 42:9</p> <p>opening ^[1] - 45:15</p> <p>opposed ^[2] - 18:20, 21:5</p> <p>opposite ^[2] - 25:21, 26:15</p> <p>orange ^[1] - 11:2</p> <p>order ^[2] - 25:6, 45:18</p> <p>ordinary ^[36] - 12:21, 18:7, 23:3, 25:7, 27:1, 27:16, 27:22, 28:2, 30:7, 30:14, 31:24, 32:2, 34:12, 34:13, 39:24, 41:1, 41:20, 43:12, 44:3, 44:13, 44:23, 44:25, 45:3, 46:12, 47:1, 47:23, 48:15, 49:3, 49:8, 50:15, 52:3, 52:6, 53:7, 54:12, 56:21, 57:9</p> <p>Organism ^[1] - 21:2</p> <p>orient ^[1] - 30:16</p> <p>origin ^[1] - 26:22</p> <p>original ^[2] - 15:9, 15:21</p> <p>origins ^[1] - 21:6</p> <p>otherwise ^[1] - 44:13</p> <p>ourselves ^[1] - 30:16</p> <p>own ^[5] - 15:24, 22:2, 40:24, 44:9, 49:1</p>	<p>47:19, 48:2, 48:18, 48:25</p> <p>PAR ^[3] - 1:3, 1:4, 1:4</p> <p>Par's ^[10] - 9:7, 14:4, 17:20, 18:5, 22:13, 23:4, 43:15, 47:10, 51:13, 54:11</p> <p>paragraph ^[1] - 43:10</p> <p>parameters ^[1] - 6:9</p> <p>parenteral ^[1] - 46:16</p> <p>parenthetical ^[4] - 7:18, 16:18, 26:24, 41:20</p> <p>part ^[13] - 5:25, 6:1, 14:12, 18:19, 26:1, 28:24, 32:15, 36:25, 52:7, 54:15, 55:25, 56:23, 57:1</p> <p>particular ^[19] - 5:12, 5:20, 5:23, 6:16, 15:15, 16:8, 18:6, 30:19, 31:11, 31:20, 35:13, 35:15, 36:4, 37:1, 47:1, 47:3, 48:9, 51:11</p> <p>particulars ^[1] - 52:24</p> <p>parties ^[1] - 18:8</p> <p>parties' ^[4] - 18:4, 23:18, 23:24, 41:18</p> <p>parts ^[1] - 47:21</p> <p>passage ^[4] - 26:23, 43:20, 48:17, 49:10</p> <p>passages ^[3] - 25:14, 26:6, 53:24</p> <p>patent ^[59] - 6:18, 6:21, 9:22, 10:17, 11:15, 11:20, 11:23, 13:1, 20:10, 22:16, 24:5, 24:13, 24:24, 25:6, 26:3, 26:14, 27:25, 29:2, 30:6, 30:17, 30:18, 30:19, 34:20, 35:15, 39:15, 40:24, 41:9, 41:22, 41:24, 43:20, 44:7, 44:9, 44:13, 44:20, 44:21, 45:2, 45:4, 45:16, 45:22, 45:23, 46:7, 46:12, 46:18, 46:22, 47:17, 47:22, 48:10, 49:1, 49:20, 49:22, 49:24, 50:7, 50:20, 51:5, 51:17, 52:23, 58:3, 58:17</p> <p>patentable ^[3] - 36:6, 38:25, 52:25</p> <p>patented ^[1] - 41:14</p> <p>patentee ^[1] - 15:25</p> <p>patentees ^[1] - 35:16</p> <p>patents ^[6] - 4:25,</p>
N				
<p>nail ^[1] - 51:24</p> <p>Nakul ^[1] - 3:18</p> <p>NAKUL ^[1] - 2:3</p> <p>name ^[2] - 3:12, 27:12</p> <p>narrow ^[2] - 11:22, 49:18</p> <p>narrower ^[2] - 11:19,</p>				
O				
	<p>objective ^[2] - 48:12, 49:7</p> <p>observed ^[2] - 50:24, 51:2</p> <p>obvious ^[1] - 39:23</p> <p>obviously ^[1] - 33:8</p> <p>occur ^[2] - 23:15, 28:10</p> <p>occurred ^[1] - 55:2</p> <p>occurring ^[3] - 22:17, 26:15, 26:25</p> <p>occurs ^[2] - 21:7, 23:13</p> <p>OF ^[1] - 1:1</p> <p>offered ^[1] - 36:13</p> <p>office ^[2] - 39:15, 52:23</p> <p>Official ^[1] - 1:23</p> <p>oftentimes ^[1] - 23:10</p> <p>once ^[1] - 43:7</p> <p>one ^[56] - 4:17, 6:24, 7:5, 7:17, 8:9, 9:18, 9:22, 9:23, 10:15, 11:25, 12:3, 12:13,</p>			
P				
			<p>PA ^[1] - 1:21</p> <p>page ^[3] - 28:8, 37:22, 45:15</p> <p>pages ^[3] - 12:8, 19:3, 59:19</p> <p>Paki ^[1] - 3:17</p> <p>Par ^[18] - 9:9, 12:3, 12:12, 12:17, 17:11, 23:2, 24:1, 24:9, 37:23, 41:18, 42:16, 43:4, 43:21, 47:4,</p>	

<p>5:16, 12:8, 13:12, 19:3, 30:17</p> <p>patient [16] - 5:12, 7:4, 8:14, 8:20, 9:13, 9:16, 12:23, 12:25, 13:13, 15:23, 16:4, 16:8, 56:20, 56:22, 56:24, 57:10</p> <p>patient's [1] - 8:14</p> <p>patients [3] - 35:11, 35:13, 36:22</p> <p>people [5] - 7:1, 16:10, 32:1, 35:17, 36:23</p> <p>peptide [2] - 19:11, 21:3</p> <p>peptides [4] - 23:10, 24:13, 50:12, 54:25</p> <p>per [8] - 5:21, 8:11, 9:11, 10:8, 14:21, 14:22, 14:25, 16:8</p> <p>percent [18] - 49:11, 49:12, 49:14, 49:16, 49:25, 50:1, 50:2, 50:8, 50:14, 50:25, 51:1, 51:3, 51:4</p> <p>percentage [1] - 50:13</p> <p>percentages [1] - 50:11</p> <p>perfectly [1] - 59:15</p> <p>perform [2] - 6:20, 58:25</p> <p>performance [1] - 56:3</p> <p>performed [4] - 54:14, 55:25, 58:21, 58:22</p> <p>perhaps [1] - 60:25</p> <p>permit [1] - 59:18</p> <p>permits [1] - 42:24</p> <p>person [26] - 27:1, 27:16, 27:21, 34:11, 34:12, 39:23, 41:1, 43:12, 44:2, 44:12, 44:23, 44:25, 46:12, 46:17, 46:25, 47:23, 48:15, 49:2, 49:8, 50:15, 52:3, 52:6, 52:11, 53:7, 56:20, 57:8</p> <p>perspective [2] - 16:15, 34:11</p> <p>persuasion [1] - 34:4</p> <p>persuasive [1] - 35:1</p> <p>pH [2] - 6:10, 36:4</p> <p>Ph.D [1] - 41:16</p> <p>pharmaceutical [20] - 5:1, 6:7, 11:4, 23:3, 35:12, 36:19, 36:20, 38:5, 38:6, 38:8, 39:1, 39:2, 39:3,</p>	<p>39:25, 40:2, 43:18, 44:10, 46:13, 47:11, 54:19</p> <p>PHARMACEUTICAL [1] - 1:3</p> <p>pharmaceutically [5] - 30:24, 38:4, 40:4, 40:6, 47:14</p> <p>Pharmacopeia [1] - 26:18</p> <p>phase [3] - 56:13, 56:14, 56:17</p> <p>Philadelphia [1] - 1:21</p> <p>phrase [9] - 30:17, 31:1, 31:5, 31:25, 42:1, 42:9, 42:17, 42:23, 46:21</p> <p>phrases [2] - 30:5, 42:7</p> <p>pick [3] - 41:15, 45:4, 53:5</p> <p>piece [1] - 17:8</p> <p>pieces [1] - 53:6</p> <p>pigs [1] - 18:18</p> <p>ping [1] - 4:10</p> <p>ping-pong [1] - 4:10</p> <p>places [1] - 26:14</p> <p>plain [10] - 9:17, 12:21, 13:3, 13:16, 14:5, 14:9, 14:10, 17:9, 17:17, 54:12</p> <p>plaintiff [1] - 46:1</p> <p>Plaintiff [2] - 1:17, 1:21</p> <p>plaintiffs [4] - 3:9, 17:25, 22:18, 54:8</p> <p>Plaintiffs [1] - 1:6</p> <p>plate [1] - 60:17</p> <p>play [1] - 11:13</p> <p>plays [1] - 30:24</p> <p>Plaza [1] - 2:7</p> <p>plurality [1] - 54:25</p> <p>plus [1] - 30:9</p> <p>point [13] - 7:8, 7:22, 11:18, 16:3, 28:17, 33:8, 33:11, 34:15, 34:18, 53:21, 53:23, 58:19, 59:10</p> <p>pointed [3] - 36:4, 43:21, 52:15</p> <p>pointer [1] - 56:11</p> <p>points [1] - 28:6</p> <p>polypeptide [1] - 26:8</p> <p>pong [1] - 4:10</p> <p>poor [1] - 35:24</p> <p>portion [4] - 21:8, 28:25, 29:3, 29:23</p> <p>portions [1] - 46:6</p> <p>POSA [5] - 41:10, 41:11, 44:17, 44:18</p>	<p>position [7] - 23:14, 36:11, 41:21, 44:8, 57:3, 57:15, 57:16</p> <p>possible [4] - 17:3, 17:5, 50:17, 61:4</p> <p>possibly [1] - 36:14</p> <p>post [1] - 46:23</p> <p>powder [1] - 19:21</p> <p>practical [1] - 18:21</p> <p>practically [1] - 39:23</p> <p>practice [3] - 14:7, 17:5, 58:11</p> <p>practiced [1] - 58:1</p> <p>preamble [2] - 42:2, 42:3</p> <p>preceded [1] - 28:12</p> <p>precedes [1] - 28:23</p> <p>preferred [3] - 12:5, 12:6, 12:7</p> <p>prepared [2] - 18:20, 21:21</p> <p>preponderance [1] - 55:21</p> <p>present [8] - 10:11, 13:18, 53:23, 55:5, 56:7, 56:9, 57:1, 57:5</p> <p>presentation [4] - 15:6, 15:13, 43:23, 52:19</p> <p>pressure [5] - 5:11, 6:6, 16:12, 36:23, 36:24</p> <p>presumption [1] - 58:13</p> <p>primary [1] - 26:7</p> <p>Princeton [3] - 1:17, 2:4, 3:13</p> <p>principal [1] - 34:22</p> <p>problem [8] - 13:23, 35:22, 36:17, 38:22, 40:11, 48:3, 49:1, 50:19</p> <p>problematic [2] - 25:11, 44:8</p> <p>problems [2] - 35:18, 51:19</p> <p>proceed [1] - 4:3</p> <p>Proceedings [1] - 1:25</p> <p>PROCEEDINGS [1] - 3:1</p> <p>process [1] - 22:22</p> <p>produced [2] - 1:25, 51:11</p> <p>product [14] - 5:7, 6:2, 13:2, 23:4, 23:5, 31:12, 35:12, 36:4, 36:20, 38:8, 40:6, 55:25, 56:1</p>	<p>PRODUCTS [1] - 1:4</p> <p>products [6] - 26:22, 38:7, 39:2, 39:3, 40:2</p> <p>prohormone [1] - 25:25</p> <p>proof [7] - 33:15, 40:21, 53:10, 53:19, 55:21, 59:3, 59:5</p> <p>proper [1] - 23:1</p> <p>properties [63] - 8:4, 8:8, 8:9, 9:4, 10:1, 10:4, 10:5, 11:16, 11:17, 12:22, 12:24, 14:11, 31:4, 31:15, 31:22, 33:6, 35:8, 37:6, 37:8, 37:13, 37:16, 37:21, 37:23, 39:16, 39:19, 40:5, 40:25, 41:14, 41:15, 41:17, 41:21, 43:1, 43:6, 43:7, 43:11, 43:16, 43:17, 43:22, 43:24, 44:4, 45:5, 45:20, 46:1, 46:19, 46:24, 47:1, 47:4, 47:10, 47:18, 47:19, 47:21, 47:24, 48:2, 48:4, 48:11, 48:13, 48:18, 48:20, 49:10, 55:18, 57:5, 58:5</p> <p>property [11] - 44:6, 45:16, 45:25, 46:3, 48:20, 48:21, 48:24, 49:2, 50:18, 51:9, 51:12</p> <p>proposal [2] - 22:13, 36:11</p> <p>proposed [4] - 7:16, 18:5, 18:8</p> <p>prosecution [7] - 17:18, 33:5, 36:3, 38:24, 48:12, 52:21, 53:2</p> <p>protected [2] - 12:10, 12:11</p> <p>prove [4] - 15:19, 33:21, 40:17, 44:19</p> <p>provide [8] - 10:7, 22:2, 25:16, 36:9, 38:5, 46:23, 48:12</p> <p>provided [3] - 38:20, 42:25, 43:2</p> <p>providing [3] - 6:7, 11:6, 35:3</p> <p>proving [1] - 34:3</p> <p>pump [2] - 10:23, 56:15</p> <p>purity [2] - 50:6, 50:8</p> <p>purporting [1] - 50:17</p>	<p>purports [2] - 49:21, 50:23</p> <p>purposes [3] - 19:25, 21:21, 38:13</p> <p>push [1] - 10:23</p> <p>put [10] - 7:5, 8:14, 16:19, 19:24, 20:6, 20:12, 35:20, 51:15, 55:20, 56:15</p>
Q				
<p>qualify [2] - 25:4, 28:1</p> <p>quantify [2] - 56:5, 56:7</p> <p>questions [3] - 31:6, 51:24, 54:3</p> <p>quickly [3] - 5:11, 28:5, 61:4</p> <p>quote [1] - 37:22</p> <p>quotes [1] - 42:23</p>				
R				
<p>raise [2] - 5:3, 5:10</p> <p>raised [2] - 28:6, 36:25</p> <p>raises [1] - 31:6</p> <p>Randy [1] - 60:12</p> <p>range [1] - 11:25</p> <p>ranges [1] - 11:12</p> <p>rare [2] - 5:17, 16:6</p> <p>rate [6] - 5:12, 5:20, 5:22, 6:16, 16:8, 16:12</p> <p>rather [3] - 17:19, 25:18, 49:7</p> <p>ratios [1] - 50:12</p> <p>reach [1] - 53:6</p> <p>read [15] - 4:2, 12:14, 13:1, 16:2, 23:19, 23:22, 24:20, 27:6, 41:8, 41:11, 41:14, 44:18, 44:23, 48:11, 50:15</p> <p>readily [1] - 40:15</p> <p>reading [8] - 7:1, 25:12, 29:21, 41:7, 44:13, 45:2, 46:23, 57:8</p> <p>reads [2] - 52:4, 52:5</p> <p>real [4] - 7:1, 8:1, 8:12, 9:8</p> <p>really [11] - 4:20, 5:2, 12:3, 16:8, 18:13, 18:21, 31:6, 31:15, 36:24, 37:14, 39:17</p> <p>reason [8] - 7:11, 11:11, 19:24, 22:14, 24:12, 41:8, 46:25</p>				

<p>reasonable [6] - 33:23, 34:14, 34:17, 37:14, 43:12, 48:14</p> <p>reasoned [1] - 4:13</p> <p>reasons [3] - 24:3, 35:1, 44:5</p> <p>recent [3] - 32:14, 34:23, 35:7</p> <p>recently [1] - 22:15</p> <p>recite [1] - 44:14</p> <p>recited [6] - 30:10, 30:12, 30:22, 35:14, 42:11, 42:23</p> <p>recites [2] - 42:3, 54:19</p> <p>recognize [1] - 47:23</p> <p>recognized [1] - 30:6</p> <p>record [2] - 3:7, 39:21</p> <p>recorded [1] - 1:25</p> <p>red [1] - 7:17</p> <p>refer [5] - 19:9, 23:6, 24:17, 27:22, 29:22</p> <p>reference [10] - 4:23, 19:18, 20:17, 21:14, 21:16, 22:19, 22:25, 28:21, 28:22, 47:3</p> <p>Reference [1] - 28:11</p> <p>referenced [2] - 19:1, 38:18</p> <p>references [3] - 19:10, 29:5, 38:16</p> <p>referencing [1] - 29:25</p> <p>referred [3] - 10:21, 38:11, 57:25</p> <p>referring [9] - 19:5, 19:22, 21:17, 21:20, 22:2, 28:19, 37:24, 38:6</p> <p>refers [4] - 24:7, 24:24, 29:7, 52:10</p> <p>reflect [1] - 16:8</p> <p>reflects [2] - 14:19, 15:24</p> <p>refrigerated [1] - 5:9</p> <p>refrigerator [2] - 6:12, 15:16</p> <p>regard [2] - 9:5, 9:13</p> <p>regarding [4] - 7:20, 31:16, 40:18, 52:16</p> <p>regulation [4] - 28:7, 28:9, 28:16, 29:21</p> <p>regulations [2] - 24:12, 24:16</p> <p>Reid [1] - 60:12</p> <p>relate [1] - 47:11</p> <p>related [1] - 50:21</p> <p>relates [2] - 28:7, 36:17</p> <p>relationship [1] - 12:1</p> <p>relative [2] - 34:7,</p>	<p>50:25</p> <p>relevant [3] - 29:1, 29:17, 34:11</p> <p>reliance [1] - 25:11</p> <p>relied [6] - 34:22, 34:23, 45:19, 51:16, 53:22, 54:2</p> <p>relies [3] - 12:3, 12:12, 17:20</p> <p>rely [3] - 14:8, 26:6, 26:20</p> <p>relying [1] - 34:19</p> <p>remarkable [1] - 37:22</p> <p>reminded [1] - 59:8</p> <p>remove [1] - 16:18</p> <p>REMUS [11] - 2:6, 3:15, 7:11, 14:17, 57:15, 59:7, 59:21, 60:1, 60:7, 60:19, 61:6</p> <p>Remus [1] - 3:14</p> <p>render [1] - 41:23</p> <p>reply [2] - 15:5, 34:22</p> <p>Reporter [1] - 1:23</p> <p>reports [1] - 47:12</p> <p>representation [1] - 9:8</p> <p>reproduced [3] - 24:17, 25:1, 26:17</p> <p>require [7] - 5:8, 5:20, 8:3, 24:8, 24:13, 45:3, 58:24</p> <p>required [12] - 8:5, 8:8, 8:23, 9:4, 9:14, 13:4, 14:12, 18:19, 22:1, 54:12, 59:3, 59:6</p> <p>requires [5] - 45:7, 45:8, 54:14, 54:18, 54:21</p> <p>requiring [1] - 9:3</p> <p>requisite [1] - 35:4</p> <p>resolving [1] - 60:23</p> <p>respect [8] - 23:19, 25:22, 29:22, 46:10, 47:5, 47:10, 47:15, 52:24</p> <p>respond [2] - 4:10, 28:5</p> <p>rest [3] - 35:25, 59:15, 60:19</p> <p>results [1] - 51:11</p> <p>rewrite [2] - 13:17, 14:9</p> <p>rewriting [1] - 13:6</p> <p>RHOAD [18] - 1:16, 3:8, 3:20, 17:1, 17:24, 18:4, 18:24, 19:2, 28:5, 30:3, 32:9, 32:15, 33:2,</p>	<p>33:14, 33:20, 45:7, 51:23, 53:21</p> <p>Rhoad [6] - 3:8, 17:24, 23:16, 41:25, 42:6, 43:25</p> <p>Rhoad's [1] - 43:23</p> <p>rigid [1] - 21:25</p> <p>Road [1] - 2:3</p> <p>Robert [1] - 3:8</p> <p>ROBERT [1] - 1:16</p> <p>role [1] - 13:14</p> <p>rooting [1] - 60:11</p> <p>Roszel [1] - 2:3</p> <p>roughly [1] - 19:3</p> <p>rule [2] - 9:3, 13:9</p> <p>ruled [3] - 4:14, 7:14, 9:1</p> <p>ruling [1] - 18:11</p> <p>run [1] - 57:11</p> <p>running [2] - 56:24</p>	<p>24:17, 26:20</p> <p>see [11] - 4:4, 7:25, 8:7, 8:9, 10:6, 15:6, 20:5, 20:10, 23:9, 23:12, 58:15</p> <p>seek [1] - 22:23</p> <p>sell [2] - 55:12</p> <p>selling [2] - 55:18, 55:25</p> <p>Seltzer [1] - 7:5</p> <p>semiclosed [1] - 46:21</p> <p>sense [3] - 4:18, 5:19, 32:9</p> <p>sentence [7] - 37:24, 37:25, 38:4, 38:9, 38:16, 38:19, 46:5</p> <p>separate [3] - 28:25, 56:4, 56:17</p> <p>septic [1] - 36:24</p> <p>sequence [49] - 18:6, 19:4, 19:7, 19:9, 19:11, 19:15, 19:18, 19:21, 19:23, 20:2, 20:4, 20:5, 20:11, 20:20, 20:24, 20:25, 21:1, 21:2, 21:3, 21:14, 22:7, 23:9, 23:23, 24:6, 24:10, 24:14, 24:15, 24:19, 24:25, 25:2, 25:10, 25:20, 27:12, 28:10, 28:11, 28:12, 28:15, 28:17, 28:18, 28:23, 28:24, 29:1, 29:2, 29:4, 29:22, 50:9</p> <p>sequences [1] - 23:11</p> <p>set [9] - 10:15, 10:16, 15:6, 15:20, 15:24, 36:11, 36:15</p> <p>several [4] - 6:7, 26:6, 42:6, 54:20</p> <p>SHAH [1] - 2:3</p> <p>Shah [1] - 3:18</p> <p>SHARON [1] - 1:20</p> <p>Sharon [2] - 3:11, 54:7</p> <p>shock [1] - 36:24</p> <p>short [1] - 53:9</p> <p>show [3] - 5:4, 45:19, 59:4</p> <p>showing [1] - 8:18</p> <p>shown [2] - 20:15, 23:7</p> <p>shows [8] - 4:21, 9:21, 17:18, 19:15, 47:3, 49:6, 49:24, 56:2</p> <p>side [8] - 41:18, 43:23, 47:4, 48:17</p> <p>silent [2] - 4:25, 7:20</p> <p>similar [2] - 13:18,</p>	<p>57:16</p> <p>similarity [1] - 50:9</p> <p>simpler [1] - 23:12</p> <p>simply [8] - 11:3, 11:22, 17:20, 29:2, 29:11, 40:17, 58:9, 58:21</p> <p>simultaneous [1] - 59:24</p> <p>sit [2] - 5:21, 16:10</p> <p>sits [1] - 15:16</p> <p>sitting [1] - 56:22</p> <p>situation [5] - 5:10, 5:17, 13:17, 13:18, 59:12</p> <p>six [3] - 49:17, 58:16, 58:17</p> <p>ski [1] - 60:9</p> <p>skill [30] - 16:13, 27:1, 27:22, 32:2, 33:22, 34:12, 34:13, 39:24, 41:1, 43:12, 44:3, 44:13, 44:23, 44:25, 45:3, 46:12, 46:17, 47:1, 47:23, 48:13, 48:15, 49:3, 49:8, 50:15, 52:3, 52:6, 53:7, 55:17, 56:21, 57:9</p> <p>skill's [1] - 27:16</p> <p>skip [1] - 45:18</p> <p>slate [1] - 9:5</p> <p>slide [39] - 4:21, 6:3, 7:14, 7:15, 7:24, 8:7, 8:16, 9:7, 9:19, 9:20, 9:21, 11:1, 11:14, 12:22, 13:20, 14:18, 15:5, 20:5, 20:13, 21:1, 21:16, 23:7, 25:1, 28:8, 28:21, 36:7, 36:15, 37:25, 38:4, 47:2, 49:6, 49:24, 50:20, 56:2, 58:3, 58:16, 58:18</p> <p>slides [2] - 19:10, 29:23</p> <p>smooth [1] - 26:9</p> <p>sold [1] - 57:2</p> <p>solely [1] - 57:22</p> <p>solid [1] - 40:13</p> <p>solution [2] - 7:6, 26:10</p> <p>solutions [1] - 35:20</p> <p>solvents [1] - 56:13</p> <p>sometimes [2] - 7:25, 16:5</p> <p>somewhat [1] - 37:22</p> <p>sorry [2] - 45:13, 53:21</p> <p>sort [2] - 30:11, 31:9</p>
--	---	--	---	---

<p>sought [1] - 22:18</p> <p>Soule [1] - 1:23</p> <p>speaking [1] - 60:25</p> <p>spec [1] - 35:25</p> <p>specific [12] - 8:8, 8:10, 11:10, 11:19, 15:18, 24:8, 24:10, 24:14, 25:19, 29:22, 42:18, 53:24</p> <p>specifically [23] - 10:9, 12:22, 12:24, 13:7, 19:5, 19:8, 20:4, 20:17, 21:17, 22:6, 26:21, 27:20, 27:22, 27:25, 28:9, 36:8, 38:10, 38:12, 38:15, 44:14, 50:5, 52:10, 57:18</p> <p>specification [73] - 6:19, 6:23, 7:2, 7:7, 9:20, 10:20, 10:23, 12:5, 12:9, 15:24, 17:18, 19:8, 19:13, 19:22, 20:22, 21:8, 22:1, 22:5, 24:18, 24:24, 25:13, 25:20, 25:22, 25:24, 26:2, 26:4, 26:14, 27:2, 27:8, 27:25, 28:10, 29:3, 33:5, 38:21, 38:23, 40:23, 40:24, 43:21, 44:7, 44:13, 44:20, 45:2, 45:5, 45:9, 45:17, 45:22, 45:24, 46:7, 46:13, 46:18, 46:22, 47:17, 47:22, 47:25, 48:5, 48:11, 49:1, 49:5, 49:21, 49:22, 50:7, 50:15, 51:5, 51:9, 51:17, 52:16, 53:6, 58:15, 58:19</p> <p>specificity [2] - 12:2, 48:2</p> <p>specifics [1] - 46:3</p> <p>specified [3] - 54:10, 55:5, 55:17</p> <p>specifies [1] - 55:1</p> <p>specify [1] - 55:15</p> <p>specifying [2] - 10:12, 55:20</p> <p>spell [2] - 22:20, 47:25</p> <p>spelled [4] - 23:17, 45:24, 47:18, 48:8</p> <p>spells [2] - 48:18, 58:6</p> <p>spent [1] - 60:22</p> <p>stability [28] - 35:24, 36:2, 36:4, 36:9, 36:17, 36:18, 37:24,</p>	<p>38:3, 38:22, 40:15, 40:16, 43:18, 44:1, 47:5, 47:7, 48:23, 49:6, 49:9, 49:20, 49:22, 50:18, 50:21, 52:16, 52:18, 52:22, 52:25, 53:4, 53:14</p> <p>stable [1] - 47:8</p> <p>stage [3] - 43:4, 51:15, 51:21</p> <p>stand [1] - 29:21</p> <p>standard [7] - 32:4, 33:19, 33:20, 33:25, 40:19, 48:7, 53:10</p> <p>standards [3] - 33:15, 33:21, 34:5</p> <p>start [5] - 4:8, 9:9, 15:15, 54:17, 56:12</p> <p>starting [2] - 9:9, 43:21</p> <p>starts [1] - 35:21</p> <p>state [4] - 24:18, 25:15, 26:4, 26:14</p> <p>State [1] - 1:10</p> <p>statement [2] - 36:7, 37:22</p> <p>statements [1] - 4:22</p> <p>States [1] - 3:2</p> <p>states [4] - 25:24, 26:2, 26:21, 29:21</p> <p>STATES [2] - 1:1, 1:13</p> <p>stationary [1] - 56:17</p> <p>stenography [1] - 1:25</p> <p>step [12] - 6:7, 6:11, 6:13, 6:15, 10:2, 10:6, 43:5, 48:3, 51:19, 54:14, 55:24</p> <p>steps [2] - 6:7, 42:19</p> <p>sterile [1] - 26:10</p> <p>STERILE [1] - 1:4</p> <p>still [4] - 8:22, 8:24, 44:5, 60:11</p> <p>stipulated [1] - 18:9</p> <p>storage [1] - 5:8</p> <p>stored [4] - 5:8, 50:23, 50:24, 51:2</p> <p>storing [1] - 6:11</p> <p>story [1] - 50:10</p> <p>straightforward [1] - 8:2</p> <p>Street [2] - 1:10, 1:20</p> <p>stronger [1] - 51:20</p> <p>strongest [1] - 12:13</p> <p>strongly [1] - 12:4</p> <p>structural [1] - 19:21</p> <p>structure [5] - 6:4, 11:16, 19:17, 20:12, 20:19</p> <p>studied [1] - 47:9</p> <p>studies [1] - 47:13</p>	<p>stuff [1] - 37:11</p> <p>subcutaneous [1] - 46:15</p> <p>subject [2] - 8:7, 23:5</p> <p>submissions [1] - 59:24</p> <p>submit [2] - 59:2, 59:19</p> <p>submits [2] - 9:16, 17:16</p> <p>submitted [5] - 6:25, 17:3, 39:19, 52:22</p> <p>subsequent [1] - 25:2</p> <p>substances [1] - 19:6</p> <p>success [1] - 47:9</p> <p>sufficient [2] - 41:1, 48:2</p> <p>sufficiently [6] - 43:11, 45:21, 48:4, 48:14, 48:25, 49:2</p> <p>suitability [7] - 37:1, 38:15, 40:8, 40:12, 43:19, 44:12, 47:15</p> <p>suitable [1] - 36:20</p> <p>Suite [2] - 1:16, 2:7</p> <p>summarized [1] - 13:19</p> <p>Sunday [1] - 60:20</p> <p>Super [1] - 60:5</p> <p>superfluous [1] - 58:11</p> <p>supported [1] - 54:11</p> <p>Supreme [2] - 33:24, 34:2</p> <p>swallow [1] - 7:5</p> <p>synthesis [1] - 26:6</p> <p>synthesized [2] - 23:15, 25:25</p> <p>synthetic [26] - 18:24, 21:3, 21:15, 21:17, 22:5, 22:8, 22:21, 22:24, 23:21, 24:22, 24:25, 25:8, 25:19, 25:23, 26:4, 26:5, 26:11, 26:17, 26:24, 26:25, 27:4, 29:6, 29:8, 29:13, 29:19, 29:25</p> <p>synthetically [4] - 18:20, 20:25, 21:5, 21:21</p> <p>syringe [4] - 5:18, 5:21, 10:23, 16:11</p>	<p>talks [1] - 6:19</p> <p>tautology [1] - 16:22</p> <p>technique [2] - 56:4, 56:9</p> <p>temperature [10] - 13:23, 13:24, 14:3, 49:15, 50:2, 50:23, 51:4, 53:12, 53:13</p> <p>ten [3] - 51:4, 59:19, 59:25</p> <p>term [23] - 4:7, 4:9, 17:23, 18:1, 21:24, 22:11, 23:5, 23:23, 24:11, 25:7, 27:16, 30:3, 30:5, 30:18, 30:21, 35:24, 41:19, 41:21, 54:9, 54:11, 57:15</p> <p>terms [12] - 4:7, 13:16, 23:11, 30:18, 31:7, 34:5, 34:7, 37:12, 37:20, 54:14, 57:16, 58:5</p> <p>test [10] - 55:1, 55:4, 56:1, 56:2, 56:24, 57:4, 59:12, 59:13, 59:14</p> <p>tested [2] - 19:17, 51:6</p> <p>testimony [11] - 13:15, 13:16, 14:9, 32:10, 33:9, 34:21, 35:2, 40:24, 45:23, 51:14</p> <p>testing [3] - 36:1, 50:3, 52:22</p> <p>tests [1] - 51:10</p> <p>text [1] - 28:13</p> <p>textual [1] - 16:14</p> <p>THE [53] - 1:1, 1:13, 3:4, 3:7, 3:19, 3:22, 3:25, 4:1, 4:2, 4:12, 4:16, 5:13, 7:8, 7:10, 12:19, 14:13, 14:15, 16:25, 17:22, 18:3, 18:23, 19:1, 22:10, 24:2, 28:3, 30:2, 32:8, 32:13, 33:1, 33:13, 33:19, 40:18, 41:3, 41:5, 41:10, 44:16, 44:25, 45:6, 45:12, 51:22, 53:20, 54:5, 55:8, 57:6, 57:13, 59:17, 59:23, 60:2, 60:4, 60:12, 60:14, 60:17, 60:21</p> <p>theirs [1] - 29:24</p> <p>themselves [2] - 22:25, 39:16</p> <p>theory [2] - 15:3, 15:20</p>	<p>therapeutically [1] - 46:14</p> <p>thereafter [2] - 49:18, 50:2</p> <p>thereof [1] - 30:24</p> <p>they've [3] - 5:2, 16:21, 43:24</p> <p>thinking [1] - 57:10</p> <p>third [3] - 6:13, 24:1, 27:5</p> <p>three [12] - 8:8, 28:6, 30:23, 31:2, 37:4, 42:7, 44:4, 47:10, 47:19, 47:21, 51:3</p> <p>throughout [7] - 19:8, 19:22, 20:22, 38:20, 39:10, 52:15, 58:19</p> <p>tiny [1] - 50:11</p> <p>title [1] - 25:15</p> <p>together [2] - 6:18, 36:16</p> <p>touch [2] - 13:14, 37:6</p> <p>toxic [1] - 40:3</p> <p>tracks [2] - 10:15, 10:16</p> <p>transcript [1] - 1:25</p> <p>transcription [1] - 1:25</p> <p>transdermal [1] - 46:16</p> <p>transition [4] - 42:4, 42:10, 42:13, 43:7</p> <p>transitional [9] - 30:5, 30:16, 31:1, 31:5, 42:1, 42:7, 42:9, 42:17, 46:21</p> <p>treat [3] - 35:12, 35:13, 47:13</p> <p>treated [1] - 12:9</p> <p>treating [16] - 36:21, 36:22, 38:10, 39:4, 40:9, 43:19, 44:11, 44:15, 44:22, 46:8, 47:12, 52:13, 56:20, 56:22, 56:23, 57:10</p> <p>treatment [2] - 52:8, 55:6</p> <p>Trenton [1] - 1:11</p> <p>Treschan [1] - 27:19</p> <p>trial [4] - 32:11, 32:22, 33:8</p> <p>true [5] - 10:3, 10:21, 22:6, 37:7, 52:14</p> <p>try [2] - 5:2, 22:24</p> <p>trying [6] - 22:21, 22:23, 23:19, 32:5, 46:20, 56:7</p> <p>turn [4] - 24:21, 24:23, 27:5, 47:21</p> <p>twice [2] - 4:3, 22:5</p>
--	--	---	--	---

T

table [6] - 19:14, 19:15, 19:16, 20:16, 20:17, 20:21

tail [1] - 12:16

<p>two ^[19] - 3:25, 9:25, 10:12, 10:18, 18:13, 18:21, 23:6, 25:1, 25:2, 30:11, 31:6, 43:5, 47:10, 47:20, 48:3, 51:19, 53:14, 54:16, 61:2</p> <p>two-step ^[1] - 43:5</p> <p>type ^[3] - 18:17, 31:5, 46:20</p> <p>types ^[1] - 42:7</p> <p>typically ^[1] - 5:9</p>	<p>variety ^[1] - 52:8</p> <p>various ^[6] - 17:8, 19:5, 21:13, 23:16, 36:1, 52:15</p> <p>vary ^[2] - 13:16, 50:22</p> <p>vascular ^[1] - 26:9</p> <p>vasoconstrictors ^[1] - 23:14</p> <p>vasopressin ^[110] - 5:7, 8:10, 8:18, 8:23, 9:10, 11:8, 17:3, 18:2, 18:6, 18:15, 18:17, 18:25, 19:7, 19:9, 19:11, 19:14, 19:15, 19:17, 19:20, 19:21, 19:23, 19:25, 20:4, 20:7, 20:8, 20:14, 20:15, 20:17, 20:18, 20:21, 20:23, 20:25, 21:7, 21:15, 21:19, 21:20, 21:21, 21:22, 21:24, 22:8, 22:17, 22:24, 23:7, 23:8, 23:13, 23:20, 23:23, 24:5, 24:7, 24:11, 24:22, 24:23, 25:3, 25:4, 25:9, 25:19, 25:23, 25:24, 26:2, 26:7, 26:8, 26:11, 26:16, 26:17, 26:21, 26:22, 27:3, 27:4, 27:6, 27:7, 27:8, 27:9, 27:11, 27:13, 27:14, 27:15, 27:17, 27:19, 27:20, 27:23, 27:24, 28:18, 29:8, 29:10, 29:12, 29:13, 29:15, 29:19, 30:1, 30:23, 35:10, 35:17, 35:19, 35:20, 36:2, 47:6, 47:13, 50:8, 50:22, 54:21, 56:6</p> <p>vasopressin's ^[1] - 23:2</p> <p>Vasodilator ^[1] - 23:4</p> <p>vast ^[1] - 16:4</p> <p>vein ^[1] - 8:14</p> <p>verbatim ^[3] - 44:2, 46:1, 48:24</p> <p>version ^[4] - 11:19, 11:22, 27:11, 29:14</p> <p>vial ^[4] - 5:7, 6:11, 15:15, 16:3</p> <p>view ^[4] - 32:9, 33:18, 34:10, 35:3</p> <p>violates ^[1] - 28:16</p> <p>virtually ^[4] - 49:23, 50:6, 50:9, 50:12</p> <p>viscosity ^[2] - 36:10,</p>	<p>44:7</p> <p>visit ^[1] - 3:22</p> <p>W</p> <p>wag ^[2] - 12:16, 12:19</p> <p>Wallack ^[2] - 3:13, 3:18</p> <p>WALLACK ^[1] - 2:2</p> <p>wants ^[1] - 47:19</p> <p>waste ^[3] - 56:19, 57:12</p> <p>water ^[4] - 6:10, 7:6, 31:1, 35:21</p> <p>week ^[1] - 49:16</p> <p>weekend ^[2] - 4:3, 60:22</p> <p>weeks ^[3] - 5:8, 6:12, 15:17</p> <p>weigh ^[1] - 17:8</p> <p>weighed ^[1] - 51:17</p> <p>welcome ^[2] - 3:19, 3:22</p> <p>well-reasoned ^[1] - 4:13</p> <p>Weston ^[1] - 13:19</p> <p>whatnot ^[1] - 33:18</p> <p>whereas ^[1] - 54:13</p> <p>wherein ^[2] - 15:11, 52:10</p> <p>white ^[1] - 19:20</p> <p>whole ^[3] - 6:18, 19:24, 28:16</p> <p>widget ^[9] - 55:8, 55:9, 55:10, 55:11, 55:12, 55:13, 55:16, 55:18</p> <p>wishes ^[1] - 32:17</p> <p>withstanding ^[1] - 53:1</p> <p>woefully ^[1] - 53:9</p> <p>word ^[4] - 5:4, 12:7, 16:25, 22:4</p> <p>words ^[4] - 7:25, 9:17, 26:1, 26:25</p> <p>works ^[1] - 21:10</p> <p>world ^[4] - 7:1, 8:1, 8:12, 9:9</p> <p>worry ^[1] - 32:11</p> <p>worse ^[1] - 35:22</p> <p>writing ^[1] - 9:5</p> <p>written ^[1] - 59:19</p> <p>Y</p> <p>year ^[2] - 26:20, 60:13</p> <p>yellow ^[3] - 10:1, 11:2, 58:8</p> <p>young ^[1] - 3:18</p>	<p>Z</p> <p>zero ^[1] - 50:3</p>
<p>U</p> <p>U.S ^[1] - 1:10</p> <p>U.S.C ^[1] - 43:10</p> <p>ultimately ^[1] - 17:6</p> <p>under ^[9] - 25:5, 25:6, 27:13, 31:1, 35:6, 37:9, 43:10, 46:2, 59:10</p> <p>understood ^[5] - 29:18, 30:21, 37:13, 52:5, 56:21</p> <p>unexplained ^[1] - 44:5</p> <p>unit ^[13] - 5:21, 10:4, 10:5, 10:7, 10:8, 10:11, 10:18, 10:19, 11:5, 14:20, 30:22, 42:3, 42:13</p> <p>United ^[1] - 3:2</p> <p>UNITED ^[2] - 1:1, 1:13</p> <p>units ^[1] - 14:21</p> <p>unless ^[1] - 54:3</p> <p>unrecited ^[2] - 31:11, 31:20</p> <p>unusual ^[2] - 6:22, 30:6</p> <p>up ^[6] - 8:10, 14:18, 18:1, 32:16, 32:23, 60:10</p> <p>urgent ^[1] - 56:22</p> <p>US ^[1] - 26:18</p> <p>uses ^[2] - 22:17, 42:4</p> <p>USP ^[14] - 21:19, 21:21, 26:18, 27:3, 27:11, 29:5, 29:6, 29:7, 29:8, 29:14, 29:15, 29:18, 29:19, 29:23</p>	<p>V</p> <p>vague ^[3] - 46:5, 46:18, 47:18</p> <p>vaguely ^[1] - 44:9</p> <p>validly ^[1] - 31:8</p> <p>variation ^[2] - 25:9, 51:4</p>	<p>Y</p>	